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Biomedicine,
Ethics and
Society

Dual Uses of Biomedicine: Whose responsibility?

X Annual Swedish Symposium on Biomedicine, Ethics and Society
9-10 June 2008

Keynote speakers:

Malcom Dando

University of Bradford, United Kingdom

Ingegerd Kallings

the Swedish Institute for Infectious Disease Control

Frida Kuhlau

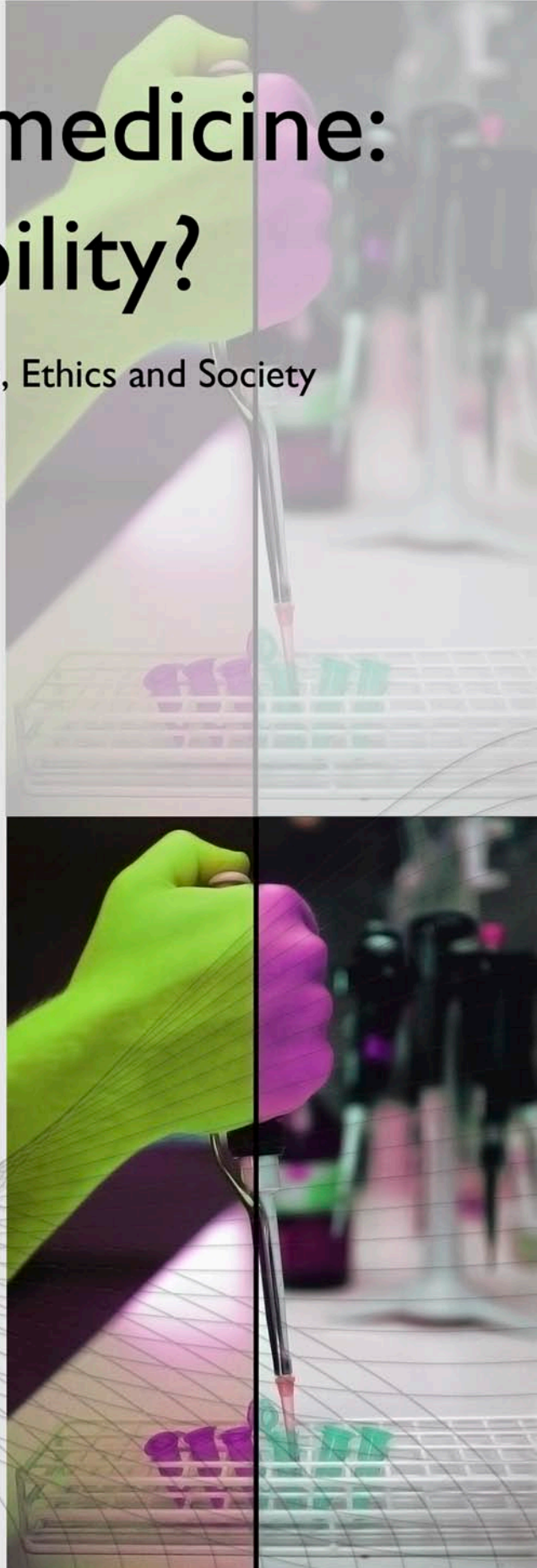
Centre for Research Ethics & Bioethics

Margaret Somerville

McGill Centre for Medicine, Ethics and Law, Canada

Centre for Research Ethics & Bioethics

In collaboration with
Stockholm International Peace Research Institute
Swedish Emergency Management Agency
Swedish Ministry for Foreign Affairs
Swedish Research Council
Riksbankens Jubileumsfond
(Bank of Sweden Tercentenary Foundation)



Dual Uses of Biomedicine: Whose responsibility?

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Sita Ramchandra **Kotnis**: *The Brain as Battlefield: Outline of an ethnographic investigation of
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**Biomedicine,
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Annual Swedish Symposia on Biomedicine, Ethics & Society: X Anniversary

The ethical dilemmas that researchers and clinicians face in their work provide the basis for multi-disciplinary networks that brings results that are relevant in practice. The annual multi-disciplinary symposia series on Biomedicine, Ethics and Society has gathered researchers from various disciplines to discuss topics ranging from the philosophy of language through bedside medical ethics and nursing ethics, behaviour and genetics, the beginning of life and priorities to the ethics of neuroscience, the limits of autonomy, what constitutes an animal and who is responsible for dual uses of biomedicine.

This series springs from a meeting on Utö in 1999 when a group of researchers from various disciplines met to discuss the profile for a research programme in biomedical ethics that was established at Uppsala University in August 1998. This group now constitutes a multi-disciplinary interfaculty Centre for Research Ethics & Bioethics at Uppsala University that also includes Medical Law. We belong to a Network for Research Ethics & Bioethics together with Karolinska Institutet and the Swedish University for Agricultural Sciences.

One of the ideas has been to allow young researchers to participate at a reasonable cost. We wish to thank the foundations and organizations that have supported this series of meetings and allowed us to invite international keynote speakers, keep the registration fees reasonable and more importantly, allowed us to offer reduced fees for PhD students.

We look forward to another ten years of interesting meetings with researchers and practitioners in various fields and academic disciplines. In 2009, the symposium will deal with Ethics in Clinical Practice, Research, and Policy.

We appreciate that you are willing to travel to the end of the archipelago to discuss biomedicine, ethics and society! We hope to see you again. Finally, a special thanks you to those who return year after year to contribute to discussions. You provide continuity and truly make this a series of symposia.

Uppsala 4 June 2008

Mats G. Hansson, Director
Centre for Research Ethics & Bioethics

Annual Swedish Symposia on Biomedicine, Ethics & Society:

Dual Uses of Biomedicine: Whose responsibility (2008)

Searching for the Animal of Animal Ethics (2007)

Rethinking Informed Consent: The limits of autonomy (2006)

Imagining the Work of the Brain: Neuroethics (2005)

Just Health Care? (2004)

Ethics at the Beginning of Life (2003)

Genetics and Human Behaviour (2002)

Medical Ethics (Vilken nytta har patienten, doktorn och sjuksköterskan av den medicinska etiken?) (2001)

The Philosophy of Linguistic Behaviour and the

Psychology of Genetic Testing (2000)

At the Intersection of Genetics and Evolutionary Biology (1999)

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Dual Uses of Biomedicine: Whose responsibility?

Welcome to the X Annual Swedish Symposium on Biomedicine, Ethics and Society

The perception of a bioterrorist threat has, in the past decade, increased and created a demand on life scientists to consider potential security implications of dual use research. The term 'dual use' can have several usages. In this symposium it refers to technologies that can have both civil and military applications, with a focus on equipment and biological material that could be misused for biological weapons purposes as well as the generation or dissemination of scientific knowledge that could be misapplied for such purposes.

The X annual Swedish Symposium on Biomedicine, Ethics and Society aims to discuss ethics, law and codes of conduct, moral obligations for life scientists, biosafety and biosecurity governance and awareness raising activities in academia. The first day consists of four keynote lectures, delivered by Malcolm Dando: Arms Control expert and Professor of International Security at Bradford University, United Kingdom, Ingegerd Kallings: Senior Medical Officer and Biosafety Advisor at the Swedish Institute for Infectious Disease Control, Frida Kuhlau: PhD Student in Bioethics at the Centre for Research Ethics and Bioethics, Uppsala University, and Margaret Somerville: Acting Director for the McGill Centre for Medicine, Ethics, and Law, Montreal, Canada. The second day consists of presentations in parallel sessions, one on challenges to monitoring and governance, and one on contextual approaches.

We wish to thank the Stockholm International Peace Research Institute, www.sipri.org, the Swedish Emergency Management Agency, www.krisberedskapsmyndigheten.se, the Swedish Ministry for Foreign Affairs, www.sweden.gov.se, the Swedish Research Council, www.vr.se and Riksbankens Jubileumsfond (Bank of Sweden Tercentenary Foundation), www.rj.se for their generous contributions that made this symposium possible.

The planning committee welcomes you to Sandhamn. We are looking forward to two days of interesting and stimulating discussions!

Stefan Eriksson, PhD
Kathinka Evers, Associate Professor
Josepine Fernow, Co-ordinator
Anna T. Högund, Associate Professor
Frida Kuhlau, MsC, PhD Student

**Centre for Research Ethics & Bioethics
Uppsala University**

sipri
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Ministry for Foreign Affairs
Sweden

 Vetenskapsrådet

 Riksbankens
Jubileumsfond

**Biomedicine,
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Programme

Monday June 9, plenary session:

Keynote lectures

- 13:00 **Welcome**
Mats G. Hansson, director, Centre for Research Ethics & Bioethics
- 13:15 **Biosafety and Biosecurity Governance in Life Science Research:
Public health aspects; explaining the concepts and their relation; ethical
relevance**
Ingegerd Kallings, the Swedish Institute for Infectious Disease Control
- 14:00 Discussion
- 14:15 **Preventing the “Life Sciences” from Becoming the “Death Sciences”:
Ethics, law and codes of conduct in dual use research**
Margaret Somerville, McGill Centre for Medicine, Ethics and Law, Canada
- 15:00 Discussion
- 15:15 Coffee
- 15:45 **Taking Due Care in Life Science: Moral obligations in dual use research**
Frida Kuhlau, Centre for Research Ethics & Bioethics
- 16:30 Discussion
- 16:45 **Raising Awareness of the Dual-Use dilemma in Academia: Experiences
and reflections**
Malcolm Dando, University of Bradford, United Kingdom
- 17:30 Discussion
- 17:45 **Plenary session ends**
- 19:00 **X anniversary dinner**

Tuesday June 10, parallel sessions:

Session I: Challenges to monitoring and governance

Session II: Contextual approaches (session ends at 10:30)

Challenges to monitoring and governance

Moderator: Ingegerd Kallings

- 08:30 **BIOSAFE – a European research project**
Åsa Szekely Björndal, PhD, Swedish Institute for Infectious Disease Control, Sweden
- 09:00 **Monitoring Dual Use of Research and its Dissemination**
Sharad S Chauhan, Indian Police Service, Punjab, India
- 09:30 **Laboratory Biosecurity Handbook**
Peter Clevestig, SIPRI, Sweden
- 10:00 **Bioethics and Biosecurity for Life Science Research**
Emmanuelle Tuerlings, Ottorino Cosivi, Andreas Reis and Tikki Pang, World Health Organization, Geneva, Switzerland

10:30 **Coffee**

Moderator: Margaret Somerville

- 11:15 **A Framework Analysis on the Role of Ethical Considerations in Past Biological Weapon Programmes, (SIPRI)**
John Hart, SIPRI, Sweden
- 11:45 **State Responsibility to Control Dual-Use Research on the Basis of International Instruments?**
Sirpa Soini, University of Helsinki, Faculty of Law, Finland
- 12:15 **Life Science Research of ‘Dual-Use’ Concern: Options for governance**
Peter Clevestig, SIPRI, Sweden
- 12:45 **What Responsibilities do Scientists in National Biodefence or Protection Against Bioterrorism Programs Have?**
Roger Roffey, FOI (Swedish Defence Research Agency), Sweden

Contextual approaches

Moderator: Malcolm Dando

- 08:30 **The Dual-Use Dilemma, Bioterrorism and Biosecurity**
David Friedman, PhD, Institute for National Security Studies (INSS), Tel-Aviv University, Israel
- 09:00 **Reviewing Dual Use Research of Concern: What is an Institution to Do?**
Timothy F. Murphy, Department of Medical Education, University of Illinois College of Medicine, USA
- 09:30 **The Brain as Battlefield: Outline of an Ethnographic Investigation of the Military Use of Neuroscience**
Sita Ramchandra Kotnis, Center of Functionally Integrative Neuroscience and Department of Anthropology, University of Aarhus, Denmark
- 10:00 **Chinese Views on Biosecurity and the Dual Use Dilemma**
Michael Barr, University of Newcastle upon Tyne, United Kingdom
- 10:30 **Coffee**
Session II ends
Symposium continues in Session I
- 13:15 **Lunch**
- 14:00 **X Anniversary Ceremonials**
- 15:00 Symposium ends, boat departs for Stockholm
17:05 Arrival (Strandvägskajen) Stockholm



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Dual Uses of Biomedicine: Whose responsibility?

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Raising Awareness of the Dual-Use dilemma in Academia: Experiences and reflections

Malcolm Dando, University of Bradford, United Kingdom

Abstract of Keynote Presentation:

The meetings of the Biological and Toxin Weapons Convention (BTWC) in 2008 will be concerned in part with awareness-raising, education, oversight and codes of conduct. This paper asks what we might best hope to gain from consideration of these topics in regard to preventing the hostile use of the modern life sciences. To that end the paper begins by noting that the threat of disease may be natural, accidental or deliberate and that deliberate misuse may come from states, sub-state groups or individuals. In regard to deliberate misuse, there is very little historical evidence of bioterrorism by sub-state groups but a century-long record of large-scale, offensive, biological weapons programmes (and use) by major states. In these historical programmes the then current cutting-edge science was used to develop biological weapons. The dual-use dilemma, therefore, is essentially this: that the modern life sciences - materials, technology and knowledge - could be misused in the same way.

The topics of the 2008 meetings are correctly analysed against that background. In the Final Declarations of the BTWC Five-Year Review Conferences since 1986, the importance of education about the Convention has been agreed, but the evidence from States Parties and our extensive work in interactive seminars with practising life scientists in 13 countries shows that there is a very low awareness of the Convention and the potential misuse of the life sciences. Clearly, States Parties should make serious efforts to correct this situation and we have suggested, for example, that a Hippocratic-style oath taken on graduation might be a simple and cost-effective initial step forward.

If there are further state-level offensive programmes in this century it is argued that they will be similar to the programme in the former Soviet Union where the military programme was hidden within biodefence, public health and commercial cloaking operations. In order to assess the value of awareness-raising, education, oversight and codes of conduct, therefore, three examples - from the available open literature - of ever deeper involvement of scientists in the illegal Soviet programmes are outlined.

In that context, a brief account is given of the developments related to codes of conduct, oversight and education since the previous BTWC meetings on codes of

conduct in 2005. The paper then investigates the extent to which such measures would have assisted the scientists described in the three examples from the Soviet programme. It is concluded that they may have helped in two but certainly not in the third example. To be effective these measures must be integrated within a much wider 'web of prevention' based on a strengthened BTWC. Therefore, it is towards this longer-term aim of having a universal, nationally implemented and internationally verifiable BTWC that the meetings in 2008 have to work and against which they should be judged.

An aware, educated and engaged life sciences community was missing during the decade-long negotiations and eventual failure to agree a legally-binding verification protocol during the 1990s. That situation should no longer be possible or acceptable when States Parties return to this issue - presumably after the 2011 Seventh Review Conference.

Biosafety and Biosecurity Governance in Life Science Research: Public health aspects; explaining the concepts and their relation; ethical relevance

Ingegerd Kallings, M.D. Senior Medical Officer, Biosafety Adviser,
Swedish Institute for Infectious Disease Control

Abstract of keynote presentation:

Biological agents are handled in laboratories for legitimate purposes e.g. public health, research and production of pharmaceuticals. Biosafety as described by the World Health Organization (WHO) is the containment principles, technologies and practices implemented to prevent unintentional exposure to pathogens, or their accidental release protecting laboratory staff, general public and the environment, whereas laboratory biosecurity deals with the protection, control and accountability for biological materials in order to prevent their loss, theft, misuse, diversion of, unauthorized access, or intentional release. National or regional control measures to prevent dissemination of biological agents and toxins with malevolent intent may be referred to as law enforcement biosecurity. Biosafety and biosecurity measures interact and a biosafety programme needs few extra measures to match up to a secure laboratory environment. Lately, managerial aspects have come into focus and a Laboratory Biorisk Management Standard has been developed. In addition to the WHO Laboratory Biosafety Manual many countries have national biosafety regulations and guidelines, in Europe based on EU Directives. International regulations for the safe transport of infectious substances have been in place since over 25 years. 'Codes of conduct' for life science researcher are being developed arising from within the scientific community. The regulatory framework for a safe and secure handling of biological agents and toxins exists, but compliance needs to be improved. However, there are attempts from the law enforcement security bodies to instigate a 'fortress approach' to bio-threats which might have detrimental effects on research and on public health. It is an obligation to safe-guard the right to exchange biological materials, technology and knowledge for research and public health purposes as well as the right to academic freedom.

Taking Due Care in Life Science: Moral obligations in dual use research

Frida Kuhlau, Centre for Research Ethics & Bioethics

Abstract of keynote presentation:

In the past decade the perception of a bioterrorist threat has increased and created a demand on life scientists to consider potential security implications of dual use research. A number of proposed moral obligations for life scientists have emerged as a response to these concerns. The reasonableness of these obligations will be discussed in relation to five criteria for what can be considered to constitute preventable harm.

Although bioterrorism might be perceived as an imminent threat, the analysis will illustrate that it is not a reasonable obligation for life scientists to either prevent or respond to. Among the more reasonable obligations that will be discussed are; duties to consider potential negative implications of one's research, safeguard the access to sensitive material, technology and knowledge and report activities of concern. Responsibility, thus, does not involve preventing the act of misuse but rather such obligations concerned with preventing foreseeable and highly probable harm. One important conclusion is that many proposed obligations are reasonable, however, not unconditionally.

Preventing the “Life Sciences” from Becoming the “Death Sciences”: Ethics, law and codes of conduct in dual use research

Margaret Somerville, McGill Centre for Medicine, Ethics and Law,
Canada

Abstract of keynote presentation:

Bluntly stated, the overall goal of implementing ethics, law and codes of conduct in dual use research is to prevent the life sciences from becoming the death sciences through bioterrorism or biowarfare.

I believe that ethics can function as one, among many, means to counter bioterrorism, provided it is embedded in science from its inception.

To achieve that goal requires knowing the principles that should inform the ethics and law that govern science; appreciating factors - such as uncertainty, complexity and potentiality - that can affect how well we can put those principles into practice on a day-to-day basis; accepting that achieving our goal is not a one-time event, but an ongoing process that requires monitoring and, when necessary, change; understanding how scientists and others view ethics and breaches of ethics; and recognizing that a conjunctive, rather than disjunctive, approach using multiple and diverse means is required to achieve the best outcome possible in terms of ethics in any given circumstances.

Further, while it is essential to focus specifically on the ethics of dual use research, we also need to have some idea of the larger, emerging “ethics picture” of which this ethics is a part. I will briefly introduce concepts, explored in my book, *The Ethical Imagination: Journeys of the Human Spirit* (House of Anansi Press, 2006), such as the relevance of multiple ways of human knowing to ethics; the need for a “shared ethics” on boundary crossing issues; the idea of “human ethics”, as well as human rights and human responsibilities; the potential of employing a concept of the “secular sacred”; the need to take account of moral risk, as well as physical risk; competing current worldviews with respect to science and its appropriate governance, in light of its impact on fundamental concepts of what it means to be human and on important societal values; and how we might make ethics an “infectious condition”.

BIOSAFE – A European research project Heading

Åsa Szekely Björndal, PhD, Swedish Institute for Infectious Disease Control, Sweden

Abstract of presentation in the session "Challenges to Monitoring and governance":

Intentional spread of human pathogens represents a considerable threat for a modern civil society. Malicious use of biological agents has also the potential to inflict damage well beyond the primary impact. Manufacturing, stockpiling and disseminating biological agents is relatively easy and cheap and their effect, in the worst case, can be comparable to the effect of nuclear or chemical weapons of mass destruction. Despite the worldwide ban on biological weapons a quarter of century ago there is no reliable information about the amount of dangerous material and equally dangerous knowhow that is out in the circulation on the international market. Deliberate release of disease causing agents has also a huge psychological impact. Even a few disturbed or disgruntled individual can terrorize a whole society over a long time as was amply demonstrated by the spreading of anthrax spores by mail in the US in 2001. Bioterrorism elicits a culture of fear in the population with potentially devastating consequences.

The BIOSAFE project is funded through the EU FP6 framework and aims to enhance the capability of public health and civil protection authorities to prepare for and respond to a deliberate release of biological agents. The project aims to identify the existing knowledge, and expertise in Europe about pathogens and toxins that are perceived as agents of threat. The project also aims to collate information on modern diagnostic technologies and on new methods to control disease outbreaks. The main deliverable of the project is a conceptual framework on the interaction of pathogens with their host and methods of countermeasures to mitigate the affects of a deliberate release.

Monitoring Dual Use of Research and its Dissemination

Dr Sharad S Chauhan, Indian Police Service, Deputy Inspector General of Police cum Joint Director, Punjab Police Academy Phillaur, Punjab, India

Abstract of presentation in the session "Challenges to monitoring and governance":

Recent developments in biological sciences have created a sense of fear of Bioterrorism. The rapid pace of development of science and technology has created a genuine fear that terrorists, criminals, non-state actors, or white-collar criminals might misuse biological sciences to create terror, economic harm or asymmetric warfare. There is a need for broad consensus for need to monitor dual use scientific research and its dissemination. Areas of concern include the mandate of research, pathogen accountability, and transportation and information security. Multifaceted approach with stakeholders like researchers, government and security officials, academicians, non-governmental agencies is required. A universally acceptable internal code of conduct and ethics with a just transparent legal sanction is required to curb nefarious dual use research. Monitoring is also needed on sister sciences like physics and chemistry which are useful in weaponization of biological agents. A balanced globalized measures are needed for control of biological agents and research for reasons of fairness and legitimacy. Monitoring is needed for all elements essential for biological event occurrence i.e. Human resources of skilled personal, a select list of pathogens universally or regionally agreed to, dual use technology and research. Strengthening of the B.T.W.C., involvement of the W.H.O., F.A.O. and O.I.E and independent think tanks like the S.I.P.R.I. and Australia group should be elicited so that genuine scientific research benefiting humanity, research in pure sciences and generative commercial activities do not suffer. Intelligence agencies should develop analytical tools and programs to create triggers that could detect any dubious dual use research or developments.

KEYWORDS: Bioterrorism; Biosecurity; Dual use research

Laboratory Biosecurity Handbook

Peter Clevestig, PhD, SIPRI, Sweden

Abstract of presentation in the session "Challenges to Monitoring and governance":

Safety in relation to life science work (Biosafety) has become a well harmonized practice in most clinical and research laboratories today, and is also becoming increasingly integrated into core education to familiarize future scientists and laboratory staff on the occupational hazards associated with working on live biological micro-organisms. These hazards focus on accidental events, and on how risks are assessed and dealt with through standard operating procedures (SOPs), personal protective equipment (PPE), and good laboratory practices (GLP).

However, security aspects regarding biological agents (Biosecurity) remain largely untold, and few stakeholders are familiar with the potential risks their work and materials could pose to society if procured by those with a malicious intent. Biosecurity describes the practices of securing dangerous materials and sensitive equipment from unauthorized individuals or groups, and may range from bioterrorist, animal rights activists to disgruntled employees with access and technical know-how.

Security issues related to life science work is a topic of much debate among policy makers and security specialists, but has not readily permeated down to the stakeholders. Recently published guidelines from the WHO, the OECD and a CEN Workshop Agreement concerning biological risks and biosecurity have initiated a dialogue between stakeholders and policy makers, but are broad documents that provide a framework for future implementation of biosecurity, and are not primarily aimed at the ground level stakeholders.

SIPRI, through financing by the Swedish Emergency Management agency (KBM) is developing a handbook on biosecurity aimed at different levels of employees at laboratory working with microbiological materials. The handbook, through its different chapters, targets the people in the laboratories performing the bulk of the scientific work (PhD students, support staff and guest researchers), the lead investigators (group leaders, senior scientists, heads of laboratories), the facility management (department heads and other administrative staff), and finally the Institutional Biosafety Committees (IBCs). The primary aim of the handbook is to raise awareness of biosecurity issues, and to hopefully provide relevant procedures and examples for increasing facility biosecurity across all levels. The procedures described aim at being simple, doable and rely on the human resources rather than expensive physical security.

Life Science Research of 'Dual-Use' Concern: Options for Governance

Peter Clevestig, PhD, SIPRI, Sweden

Abstract of presentation in the session "Challenges to Monitoring and Governance":

Governments [and non-governmental organizations (NGOs)] have increasingly scrutinized life sciences research and technology in recent years as part of efforts to prepare against possible acts of bio-terrorism. There is concern that non-state actors, seeking to cause harm through less conventional methods could remove dangerous pathogens from poorly run facilities and access the necessary scientific information from open sources. Such concerns have prompted a sort of 'soul searching' by scientists on the possible negative consequences if their research were to be used for malicious purposes. The term 'dual-use', coined first in the context of nuclear technologies following the development of the nuclear weapons, has recently been appropriated to describe life science research that could have prohibited military applications.

Some researchers, analysts and interested observers may consider that all life sciences possess varying degrees of dual-use potential, while others may focus more on specific areas, such as on increasing virulence, enhancing pathogenicity, inducing antibiotic resistance, manipulating immune responses and aerosolization of drugs. Some believe that these areas of research are of special concern, and require stricter control and oversight prior to publication and general dissemination. Others raise the issues of ethics and moral responsibilities of scientists in assessing the benefits for human, animal or plant health vs. the possible negative impacts of their work. One can also consider whether the threshold of 'legitimate' science crosses over to the boundary into research that is 'of concern'.

No single, credible scientific publication develops without reference to the prior work carried out by other scientists, and to base research (as well as applied research) or annual reviews of scientific literature. All may fall into the category of dual-use and it may not be possible to single out a specific publication as being problematic.

Another consideration is that life science research in itself is not always easily categorized into 'good' and 'bad' as is sometimes the case in the nuclear field. Increasing the virulence of one pathogen can, in some cases, be essential to discover how immune responses are initiated and adapt in order to develop

effective vaccines, or that assays in inducing antibiotic resistance can help pinpoint specific mutations to be screened for in the clinical environments. Furthermore, research outcomes raising concerns for dual-use may be fortuitous in nature.

The growing concern for misuses of life science research is not unwarranted, and it may also be in the research community's best interest to take a proactive approach towards publication of sensitive research partly in order to circumvent possible restrictions set forth by policymakers. Such approaches, together with the perceived understanding of the term 'dual-use' will be discussed in more detail after a presentation of publications in scientific literature identified as raising dual-use concern in the past.

A Framework Analysis on the Role of Ethical Considerations in Past Biological Weapon Programmes, (SIPRI)

John Hart, SIPRI, Sweden

Abstract of presentation in the session "Challenges to Monitoring and Governance":

Ethical and moral considerations are essential to education and outreach proposals. Such proposals are designed to make those in academia and research institutions more aware of the dual-purpose potential of scientific research as both a benefit and their ability to cause harm.

Education and outreach proposals are therefore continuing to be considered within the framework of the 1972 Biological and Toxin Weapons Convention (BTWC) and the 1993 Chemical Weapons Convention (CWC).

Definitions of ethics and their relation to codes of conduct and practice are presented. The political and legal context of ethics are then considered within the historical context of past biological weapon (BW) programmes, primarily the BW activities carried by Japan during World War II. Finally, the relevance of these factors are considered within the context of present-day concerns, including what might constitute a reasoned and balanced secrecy policy within bio-defence programmes and potential threats posed by non-state actors.

What Responsibilities do Scientists in National Biodefence or Protection Against Bioterrorism Programs Have?

Roger Roffey, FOI Swedish Defence Research Agency, Division of Defence Analysis, Stockholm, Sweden

Abstract of presentation in the session "Challenges to Monitoring and Governance":

Some states, like the U.S., have expanded their biodefence work significantly and the scope of the work is sometimes unclear. Governments funding biodefence programs need to demonstrate to the general public that the work is for purely defensive reasons. How effective oversight can be achieved and what responsibility do the involved scientists have? Few states make any information available on their biological defence R&D programmes. It is essential to establish national oversight mechanisms of such programs and a specific code for scientists involved (1). This should help scientists to identify the fine line between defensive and offensive R&D (2). A complementary mechanism would be to have some kind of independent international authority, scientists' ombudsman, to which scientists that are concerned with how their research is used could contact such an authority for advice. Additional requirement is that scientists must be informed of the prohibitions according to the BTWC. Enhanced efforts are needed to constrain malignant applications of biotechnology, without damaging progress in the life sciences (3). The U.S. National Academy of Sciences identified experiments that raise concern (4). In most cases though scientists should, as a principle, be trusted with self-governance. A licensing system could ultimately be an option for researchers working on dangerous pathogens and for facilities where such work is done. It has been concluded that research and security against bioterrorism is better served by policies that facilitate, rather than limit, the free flow of such information (5). Finding the right balance between scientific openness and national security is necessary.

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State Responsibility to Control Dual-Use Research on the Basis of International Instruments?

Sirpa Soini, University of Helsinki, Faculty of Law, Finland

Abstract of presentation in the session "Challenges to Monitoring and Governance":

What are the obligations and limits of the legislator in the life sciences with respect of dual-use research? This presentation examines the state responsibility and obligations arising out of the existing international instruments. Central documents are the Biological and Toxic Weapons Convention (BTWC), EU Council Regulation on export licensing (No 1334/2000 and 1183/2007), as well as UN Security Council's Resolution 1540 in 2004. Non-formal efforts are significant in practise such as the Australia group.

The examination of the international and local biosecurity regulation and policies suggests that they target to export licensing, bio-defence strategies (public health, preparedness etc.) and awareness rising among the researchers. Many scholars see these instruments incomplete and call e.g., for a universal code of conduct, whistleblower protection and international legal action to efficiently enhance a culture of responsibility. In addition, systematic risk assessment is demanded. These demands shall, however, be balanced with the freedom of science in order not to hamper the positive impact of the life sciences on human well-being.

Could or should the states impose more stringent statutory overseeing mechanisms upon the life sciences on the basis its international legal commitments to govern the dual-use research? Are measures to interfere with the freedom of science legitimate for this purpose? I will try to answer to these questions from a legal point of view.

Bioethics and Biosecurity for Life Science Research

Emmanuelle Tuerlings, Ottorino Cosivi, Scientists, Epidemic and Pandemic Alert and Response, Health Security and Environment **Andreas Reis**, Medical Officer, Ethics, Equity, Trade and Human Rights, Information, Evidence and Research, and **Tikki Pang**, Director, Research Policy and Cooperation, Information, Evidence and Research: World Health Organization, Geneva, Switzerland

Abstract of presentation in the session "Challenges to Monitoring and Governance":

Biomedical research has made rapid progress in the last decades. These advances represent both great opportunities and risks to global public health and have important ethical, legal and social implications. Many ethical questions arise, such as how to weigh the potential benefits of research against the risk for abuse, and the individual interest of researchers against the common good. Mechanisms for research oversight are being designed and codes of conducts are being promoted by different stakeholders. Because of its importance for public health, it is also important to view research in life sciences from a public health perspective.

The World Health Organization (WHO) has therefore initiated a project on life science research and global health security. The project produced a working paper, which reviewed the issue from a public health perspective. An in-house informal group comprising several departments and programmes with interests in this issue and international network of experts was also established. A scientific working group met in 2006 and identified five areas of action for WHO: education and training; preparedness for a possible major outbreak of disease; risk assessment methodologies; engagement of all stakeholders in the life science community and guidelines for oversight; capacity building at country level, including ethics, clinical practice, laboratories and research. In December 2007, the project held its first workshop in the Asian and Pacific Regions of WHO and reiterated the call for WHO action. The project is expected to produce guidelines for risk management as well as training material.

Chinese Views on Biosecurity and the Dual Use Dilemma

Michael Barr, PhD, RCUK Academic Fellow, Geography, Politics & Sociology, University of Newcastle upon Tyne, United Kingdom

Abstract of presentation in the session "Contextual Approaches":

One issue in recent attempts to strengthen international biosecurity protocols is whether the agendas of Western democracies reflect the concerns and interests of developing countries. This is important since efforts to promote responsibility and awareness of dual-use potential will have to carry global appeal to policy makers and scientific communities.

This paper uses China as a case study to address a potential divergence in interests between the developed and developing worlds. China represents a key player in biosecurity negotiations for several reasons. These include: i) China's burgeoning life science and biotechnology industries, ii) international concerns over the effectiveness of its regulatory environment, iii) its victimisation from Japanese biowarfare experiments during World War II, iv) southern China's role as a frequent site of naturally occurring infectious disease, and, v) its growing political and military power which gives China increasing influence in international negotiations.

This paper is based on preliminary fieldwork conducted in China during spring 2008. Drawing on discussions and interviews with Chinese bioethicists and life scientists in Beijing, Shanghai and Guangzhou, the paper addresses Chinese views on the appropriateness of codes of conduct, the nature of dual use educational campaigns, and the relationship between natural disease outbreaks and the malign use of biotechnology for criminal or political ends. Ultimately, the paper seeks to situate biosecurity and dual use issues into the unique context of Chinese bioethics and life sciences.

The Dual-Use Dilemma, Bioterrorism and Biosecurity

David Friedman, PhD, Institute for National Security Studies (INSS), Tel-Aviv University, Israel

Abstract of presentation in the session "Contextual Approaches":

Biotechnology, genetic engineering and molecular biology, began to develop at an unprecedented pace towards the end of the last century. Advances in DNA synthesis and cloning will soon make it possible to produce any desired gene rapidly on an industrial scale at minimal cost. Forecasts indicate that this pace will continue to increase exponentially. Although this research and development seeks to benefit humanity, hostile forces could also take advantage of recent and future biotechnological advances to harm humans on a catastrophic scale. The amount of information is freely available, and the list of organisms whose genome has been sequenced is hardly selective in terms of biological risk. Regulation of life science and biomedical research in Israel is largely limited to biosafety concerns and takes into account the unique structure and emphases of Israel's scientific research system. Biosafety oversight in academia takes place at several levels. So, Israeli researchers are no stranger to a certain amount of well-justified regulation. The big challenge now is to incorporate biosecurity concerns into this system, in particular, to upgrade measures to prevent the leakage of dangerous organisms, information and technologies to terror organizations. To this end the Israel National Security Council and the Israel Academy of Sciences and Humanities initiated a national project, Biotechnology in an Age of Terrorism, and formed a special Steering Committee on Biotechnology Research in an Age of Terrorism to analyze and report on the current situation and to recommend future action. The recommendations of this committee will be also discussed in this presentation.

Reviewing Dual Use Research of Concern: What is an Institution to Do?

Timothy F. Murphy, Professor of Philosophy in the Biomedical Sciences, Department of Medical Education, University of Illinois College of Medicine, USA

Abstract of presentation in the session "Contextual Approaches":

In 2007, the U.S. National Science Advisory Board for Biosecurity issued a 'Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information'. This report describes a framework for oversight of research that could threaten national security, public health, the environment, or natural resources. Among other things, the framework describes a role for institutional review of this kind of research. The Board would charge these committees to evaluate the conduct, oversight, and communications involved in this research. However, in its report, the Board repeatedly emphasizes the overall importance of research and the dangers of regulatory oversight. The Board even notes that institutional reviews may differ markedly about the merits and risks of proposed research. Perhaps because of these background considerations, the Board offers no specific recommendations regarding the powers that such review committees should have. By comparison, Institutional Review Boards clearly have the right to reject research involving human subjects if that research jeopardizes the rights and welfare of the subjects. If institutional review of dual use research is going to be effective, it will need some clear authority by which to require modification or prohibition of proposed research. Finally, the Board believes that its recommendations should apply to all research, not just federally financed research. If so, the government will have to find a way to require researchers in the private sector to justify their research to some kind of review boards in the same way recommended for federally-financed research.

The Brain as Battlefield: Outline of an Ethnographic Investigation of the Military Use of Neuroscience

Sita Ramchandra Kotnis, Center of Functionally Integrative Neuroscience and Department of Anthropology, University of Aarhus, Denmark

Abstract of presentation in the session "Contextual Approaches":

In recent decades there has been an immense growth and a radical change in the nature of our knowledge of the human brain. A range of techniques have made neural activity accessible to scientific scrutiny and mental and cognitive phenomena subject to biologically based empirical examinations. The new possibilities for neurologically based intervention, however, also hold an obvious potential for dual use and the new generation of neuroscientific discoveries is indeed the object of immense military attention. Presently, a considerable military financing of neuroscientific R&D manifests itself worldwide. Military appropriation of new science and technology has always been of vital importance for the maintenance of an effective defence and an up-to-date strategic security system, but neuroscience seems to inevitably radicalize such appropriation: Neuroscience not only brings classic fictions of mind-reading, telepathy, man-machine interfaces and cognitive enhancement within military reach. By virtue of the prospects for a veritable transformation of the very human material carrying technology (the soldier as warrior, as person and as biological being), neuroscience may actually prove to possess the power to redefine the conditions of warfare and national security.

In this presentation, I draw an outline of my impending PhD project about the military use of neuroscience and discuss conceptual, methodological and practical issues related to the quest for concrete knowledge about neuroscientifically informed strategies for warfare and peace keeping as well as the social, ethical and legal consequences hereof.



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