# Contextuality in Life Science Ethics:

# DUAL-USE AS A CASE STUDY



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# i. Author's Declaration

Submitted by *Louise Martha Bezuidenhout*, to the University of Exeter as a thesis for the degree of *Doctor of Philosophy* in Sociology, April 2013.

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QQ,.

Louise Martha Bezuidenhout

06/04/2013. Signed at Pretoria, South Africa.

#### ii. Abstract

In the rapidly advancing field of the life sciences, issues relating to responsibility for research are becoming a key area of discussion. Attempting to conceptualise how individual and collective responsibilities may be attributed to scientists for their research is proving both difficult and complex. Issues relating to responsibility for research may be loosely divided into two different areas. *Internal responsibilities* refer to those that scientists hold to their research and their colleagues to ensure that high quality data is produced with integrity. *Broad social responsibilities*, in contrast, reflect the social contract that scientists hold with society and refer to the commitment of scientific research to enhance and promote humanity in a manner that takes into consideration social priorities and norms.

By far, research on internal responsibilities has formed the bulk of current discussions on responsibility in life science ethics. These responsibilities have come to be represented by the field of research ethics, which focuses on the prevention of misconduct and the promotion of globally harmonised approaches to daily conduct. Research ethics has been widely endorsed, and a high level of international agreement has resulted in country-specific approaches to awareness raising and pedagogy – such as the Responsible Conduct of Research approach developed in the USA – being applicable for use in divergent social contexts.

In contrast, however, broad social issues have received comparatively less attention from the life science ethics community. Indeed, these topics often do not have a place in ethics curricula, or form "add-on" topics to ethics modules. This thesis suggests that presenting broad social issues as a progression of research ethics topics may cause considerable difficulties for pedagogy. In particular, this thesis suggests that these problems arise through the promotion of an internationally harmonised approach to research ethics, the focus on avoiding misconduct, and the reliance on informal teaching within laboratories as a fundamental aspect of perpetuating research ethics.

This thesis suggests that the crucial issue of contextual variations within ethics discussions is often marginalised. I argue such variations may have considerable implications for how scientists engage with notions of professional responsibility. Such points are particularly salient when noting that many scientists in developing countries are introduced to these topics through Western-centric ethics modules that do not take into account social, regulatory and physical variations in research environments in these countries.

In order to critically interrogate contextual variations and social responsibility, the thesis makes use of an interdisciplinary approach, using a variety of methods of investigation. The topic of dual-use – the potential for beneficial research to be misused by third parties for nefarious means – was taken as a focalising example of a broad social issue and formed the basis of comparative investigations with scientists in sub-Saharan Africa and the UK.

The fieldwork results showed significant variations between how scientists in developing countries and developed countries interacted with the topic of dualuse. It became clear that the Western-centric approach promoted by most current dual-use awareness raising initiatives, and the implicit research ethics teaching approaches in these models, caused considerable difficulties for African scientists attempting to access these discussions.

Using the theoretical framework outlined at the beginning of the thesis and the fieldwork, the thesis concludes by proposing a number of changes that could be made to the way that broad social issues are presented to scientists within ethics pedagogy.

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## v. Thanks and More Thanks!

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# vi. Definitions and Abbreviations

### **Definitions**

**Broad Social Issues**: Ethical issues arising from scientific research not directly connected to the internal issues of research ethics, and arising out of the social contract between science and society. These could include issues such as dual-use, stem cell research, or ethical issues associated with emerging technologies.

**Deontological Ethics**: A normative ethical system that judges the morality of an action based on the action's adherence to a rule or rules.

**Dual-use**: The possibility for beneficial scientific research to be misused for nefarious purposes by a third party (Miller 2007). In most current discussions this refers to the potential for well-intentioned research to be diverted into the development of bioterrorist weaponry.

**Responsible Conduct of Research**: An American approach to research ethics with a particular approach to teaching and learning.

**Research Ethics**: Field of ethics concerned with the application of fundamental ethical principles to a variety of topics involving scientific research. These include the design and implementation of research involving human experimentation, animal experimentation, various aspects of academic scandal, including scientific misconduct (such as fraud, fabrication of data and plagiarism), whistleblowing; regulation of research, etc.

**Virtue Ethics**: An ethical system that emphasizes the role of one's character and the virtues that one's character embodies for determining or evaluating ethical behavior

#### **Abbreviations**

- AAAS: American Association for the Advancement of Science
- AfBSA: African Biological Safety Association
- AIDS: Acquired Immune Deficiency Syndrome
- **ARV**: antiretroviral therapy
- AU: African Union
- BRICS: Brazil, Russia, India, China and South Africa
- **BSL**: Biological Safety Level
- BTWC: Biological and Toxic Weapons Convention
- CDC: Centre for Disease Control
- cDNA: complementary DNA
- COHRED: Council on Health Research for Development
- DHHS: Department of Health and Human Services
- EU: European Union
- FDP: Federal Demonstration Partnership
- FFP: Fabrication, falsification, plagiarism
- **GDP**: Gross Domestic Product
- GM: genetic modification
- HIV: Human Immunodeficiency Virus
- HoD: Head of Department
- HPS: History and Philosophy of Science
- IAP: InterAcademy Panel

- IAVI: International AIDS Vaccine Initiative
- ICLS: International Council for the Life Sciences
- ICRC: International Committee of the Red Cross
- **IFBA**: International Federation of Biosafety Associations
- **IIDMM**: Institute of Infectious Diseases and Molecular Medicine
- **IoM**: Institute of Medicine
- MRC: Medical Research Council
- MSDS: Material safety data sheet
- MOU: Memorandum of understanding
- NAS: National Academy of Science
- NIH: National Institute of Health
- NRC: National Research Council
- NSABB: National Science Advisory Board for Biosecurity
- **ORI**: Office of Research Integrity
- **OSM**: Open Systems Model
- **OSTP**: Office of Science and Technology Policy
- **PBMC**: peripheral blood mononuclear cells
- PI: Principle investigator
- PPE: personal protective equipment
- SCRES: Standing Committee on Responsibility and Ethics in Science
- **SOP**: Standard operating procedure
- SSK: Sociology of Scientific Knowledge
- **R&D**: research and development
- RCR: Responsible Conduct of Research

REC: Research ethics committee

**TB**: Tuberculosis

TWAS: Academy of Sciences for the Developing World

**UK**: United Kingdom

**UN**: United Nations

**UNAID:** United Nations Joint Programme on HIV/AIDS

**USA**: United States of America

**USAID**: United States Agency for International Development

**UNESCO**: United Nations Educational, Scientific and Cultural Organisation

WHO: World Health Organisation

WMD: Weapons of mass destruction

# 1. Taking Responsibility for Research

Responsibility is an important feature of discussions about the life sciences. There is an ever-increasing body of literature that addresses many different aspects of this topic – including the internal responsibilities that scientists<sup>1</sup> have in their daily research and their colleagues, and the broad responsibilities that the scientific community has to the general public. In light of the amazing advances in scientific research in the 20<sup>th</sup> and 21<sup>st</sup> century, understanding and addressing these topics will likely become an increasingly important component of future scientific endeavours. Already, a considerable amount of attention is being paid to how cultures of responsibility and awareness may be fostered within the global scientific community and how a vibrant discourse on how individual and collective responsibilities can be established within life science ethics.

Of course it stands to reason that much of the modern discourse on responsibility in scientific research has strong connections to Western ethics. In particular, life science ethics - and consequentially discussions on responsibility - have been subject to three important influences: the rise in medical bioethics, the development of human rights rhetoric, and the advent of the field of sociology of science. Together, these influences have promoted the vision of a secular, global bioethics that would ultimately be able to address the practices and products of research in an international harmonised manner. Nonetheless, as with many other fields of ethics, the notion of a global, secular ethical system is gradually coming under attack and attention is starting to be paid to issues of contextuality.

<sup>&</sup>lt;sup>1</sup> By the term "scientist" I refer to anyone who is involved in daily life undertaking of science research. This includes scientists, post-docs, technicians, and laboratory administrators. The individual scientists make up what I term a "scientific community" which can be divided into many different sub-communities depending on nationality, institutions, research stream and so forth. Although I accept undergraduate and postgraduate students are important members of the scientific community, they will always be referred to explicitly as students or learners.

The tension between the desire for a global scientific ethics and the pressures of contextuality acts as the starting point for my investigations into responsibility discourse in the life sciences. In the first portion of this chapter I examine how scientific ethics has developed in the last century, paying particular attention to why there has been a drive towards the ideal of a global ethical system and what implications this has had on responsibility discussions. I then go on to briefly highlight some of the recent criticisms against global ethical systems and then to contrast these issues to responsibility discussions in the life sciences.

In the second portion of the chapter I examine how and why the notion of a global scientific ethics has been perpetuated within ethical discourse. I propose that this is largely due to characteristic traits within the dominant field of research ethics, which focuses on the *internal responsibilities* that scientists have to their work and their colleagues. Due to widespread international agreement on the outcomes expected from this field and the specific areas of research in which it is applied, research ethics is often (mis)interpreted as a global system of ethics which may successfully moderate scientific research and prescribe behaviour for scientists. The success of research ethics initiatives and the transmissibility of the discussions across borders have, I propose, significantly influenced the manner in which contextuality is dealt (or, as the case would be, often not dealt) with in research ethics pedagogy. In order to illustrate this point, the American model of research ethics, the Responsible Conduct of Research model, is discussed in some detail.

In addition, however, another vista of responsibility is rapidly emerging which extends the scope of traditional ethics. These *broad social issues* may be seen as the result of the rapid advances in scientific research together with the development of a progressively scientifically literate and concerned general public. These broad social issues thus encapsulate the tension between society's perception of the incredible benefits that these new technologies offer, and the considerable harm that can be caused. Importantly, it must be recognised that within these issues the possibility of harm does not arise solely through misuse, but also by violating cultural perceptions of morality – and

issue that has become pertinent in discussions on stem cell research and synthetic biology.

Increasingly, thus, elements of society are beginning to question the purpose of some research, and whether this research which should not be done. Such issues - generated as they are at the interface between science and society - present complicated challenges to all involved, and how responsibility is distributed for them is far from apparent. What is undeniable, however, is that science – and therefore scientists – need to take responsibility for these issues in some fashion.

The third section of this chapter examines these broad social issues and their treatment in life science ethics, particularly highlighting the difficulties associated with developing an understanding of individual and collective responsibility for these issues. Thus, in contrast to research ethics, broad contextual issues present a field in which individual responsibilities are difficult to identify and contextual variations in discourse are highly pertinent. Nevertheless, due to extremely limited facilities, broad social issues often introduced to scientists as a small section of a larger research ethics module, and thus "immersed" in the more prominent research ethics discourse. In my analysis I propose that such a situation has the potential to cause considerable problems for building awareness of broad social issues, due to confusion arising from these contrasting ethical approaches.

These observations all contribute to the central theme for this thesis: are there problems with the way broad social issues are introduced in current ethics pedagogy, and what could be done to ameliorate them? This central theme makes it important to reiterate that this thesis does not intend to critically dissect current responsibility theories with the aim of offering a novel interpretation of responsibilities for scientific research, but rather to analyse how issues of responsibility are presented to scientists, and where these approaches may struggle to engage with scientific communities. As a considerable amount of

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the subsequent thesis focuses on developing ethical awareness amongst developing country scientists, such a distinction is not only pertinent but also highly topical.

The chapter will conclude with a brief synopsis of the areas that I perceive to be potentially problematic for any attempt to build a global culture of ethically aware scientists who engage with these broad social issues in a meaningful manner. This will form the basis for the empirical analysis of the problems associated with raising awareness of the broad social issue of dual-use, which serves as practical interrogation of these issues and will be discussed in subsequent chapters.

#### 1.1. <u>The Evolving Rhetoric of Scientific Responsibilities</u>

As detailed above, this thesis is concerned with how the concept of responsibility is introduced to scientists, and how the idea of responsible research is promoted within scientific communities. It is my proposal that a lack of sensitivity to the importance of contextuality<sup>2</sup> in much of the current ethics education, due to an over-emphasis on the idea of a global scientific ethics, has had significant repercussions on ethics pedagogy - particularly relating to the introduction of broad social issues to scientists.

I am aware that these are all highly contentious claims, and fly in the face of many accepted and well-established approaches. In order to adequately justify these proposals, it is therefore important that the modern rhetoric of responsibility in scientific research be examined in some detail. This section proposes to introduce recent developments in scientific ethics, particularly those

<sup>&</sup>lt;sup>2</sup> By "contextuality" I refer to the influence that the cultural environment may have on the development of ethical discussions and the variations that necessarily exist between communities' approaches to ethical discussions as a result of this.

that have promoted the notion of a global ethics. It is hoped that this will provide a strong basis from which to examine the issues highlighted above.

#### 1.1.1. <u>A Move Towards a Vision of Global Scientific Ethics?</u>

Scientists have long embraced the idea that they possess obligations towards humanity. Indeed, as early as 1624, Sir Francis Bacon was presenting science as *"more than an academic quest for knowledge, but rather a systematic study aiming for mastery over nature with the purpose of enabling human beings to improve their life on earth"* (Evers 2001). The recognition of such obligations has led Western science to build up a strong tradition of research being oriented towards improving humanity and contributing towards general benefits. Similarly, most discussions on responsibility over the centuries have become strongly associated with the notion of the upholding and promoting the beneficence of scientific research.

Prior to the 20<sup>th</sup> century empiricism<sup>3</sup> played a major role in influencing how the obligation towards beneficence was acted upon. The pervasive belief in "value-free" science (Kincaid 2007) emphasised the responsibilities of scientists towards data generation and the priorities of the scientific community. For practicing scientists at this time, the majority of discussions on responsibility for their work thus centred on conducting research in an open and transparent manner. In contrast, less emphasis was placed on the influence of their research on society and its possible repercussions (Kincaid 2007).

In the mid-20<sup>th</sup> century, however, the philosophy of science began to move away from these strict empirical definitions of knowledge towards more constructivist ones which viewed knowledge as a *"compilation of human-made constructions"* (Raskin 2002: 4). These movements occurred at a time when

<sup>&</sup>lt;sup>3</sup> Of which a major contributor was, of course, David Hume, who proposed the fact/value distinction in Hume, D. (1888). <u>A Treatise on Human Nature</u>. Oxford.

scientific research was also rapidly expanding in many fields of research, which spearheaded the re-examination of scientific research practices. Together, these developments emphasised the notion of science as a process instead of a system (Rheinberger 2010), with knowledge generation as a social process in which enthusiasm and scientific promise contributed towards progress (Kuhn 1962). Ethically, one of the most significant developments of these events was the gradual rejection of any justification for scientific research based solely on the neutrality of its processes and the objectivity of its product (Castello 2006). Increasingly, scientists were faced with the need consider their responsibilities beyond the narrow realm of mere knowledge generation.

In the last century, therefore, social, philosophical and scientific changes have led to increased emphasis on the moral commitment of scientists to furthering the human cause not solely by empirically accessing knowledge, but as key components in a socially-mediated process of data generation. In addition, the gradual emergence of an increasingly scientifically literate and involved general public has led scholars to reconsider the relationship between science and society. Many scholars are now referring to a "social contract", emphasising the difference between empirically sound and "socially robust" knowledge produced in a transparent and participative manner. The latter, of course, has come to epitomise modern aims of research (Gibbons 1999, Ladd 2009), and requires continual negotiation between scientists and the general public regarding the perceptions of the benefits and harms that science can lead to.

These shifts in emphasis have had significant repercussions for discussions on responsibility, as scientists are progressively called upon to consider (and at times justify) the downstream applications of their research, the impact of their research on society, and how their research practices aligned with the pervading priorities of the greater society in which it occurred. Thus, increasingly science as a discipline began to be credited not only with the power to significantly improve future quality of life but also with significant responsibilities. As outlined in the United Nations Educational, Scientific and Cultural Organisation (UNESCO) *Declaration on Science and the Use of* 

Scientific Knowledge, science: "[being] at the service of humanity as a whole, and should contribute to providing everyone with a deeper understanding of nature and society, a better quality of life and a sustainable and healthy environment for present and future generations" (UNESCO 1999). This approach exemplifies the changing attitude to responsibilities regarding what science should be done, how science should be done, and what can be expected from science and scientists.

Within this ideal of socially robust science, the *Universal Declaration of Human Rights* (UN 1948) has an important position. This declaration has played a central role in subsequent analyses of intellectual, emotional and material human rights, and has been similarly important in scientific ethics. Particularly relating to clinical trials, the Declaration placed on scientists a moral obligation towards protecting trial subjects and guarding their well-being<sup>4</sup>. In this way, scientists assumed obligations not only for safeguarding the interests of humanity in the outcome of their work, but also within their research.

Furthermore, extending the Declaration can be seen as a moral obligation to respect freedom and openness in science. As mentioned by Evers: *"in the defence of freedom of thought and expression, freedom of movement across borders, access to information and public services, and the responsibilities to respect all the other rights posited in the UN Declaration in the broad contexts of scientific research"* (Evers 2001: 62). The implications of this observation not only emphasised the responsibilities that scientists have to preserving and upholding the process of research, but their obligations in safeguarding its implementation on a global level.

The obligation for science to be involved in safeguarding fundamental human interests such as *peace, sustainable development, social equity, and respect for human rights* (Evers 2001) has come to epitomise the global rhetoric on

<sup>&</sup>lt;sup>4</sup> Similar discussions have been influential in debates on the environmental impact of scientific research.

social contracts between modern science and society. Within these discussions the modern field of bioethics, and particularly the principalist approach that it (very often) promotes, have also been highly influential in developing an ethical structure to foster these goals. Principalism, spearheaded by Beauchamp and Childress in their 1985 book *The Principles of Biomedical Ethics* (Beauchamp 2001), promotes a global, secular ethical system which is underpinned by a number of ethical norms such as autonomy, justice, beneficence and non-maleficence (dignity is sometimes also included) (Beauchamp 2001).

The considerable support for the principalist approach in medical bioethics has been influential in a similar promotion of a global ethical system to underpin scientific discourse – particularly within the life sciences. This has led to a promotion of attempts to develop and implement a "global secular ethics" within the life sciences through the identification of ethical norms such as those mentioned above. As will be discussed in the coming sections, this has had a significant influence on responsibility discourse within life science ethics.

The elaboration of responsibility in science has thus progressed over the centuries from the earlier empirically focused discussions that highlighted the moral responsibility of scientists to upholding the scientific process and producing verifiable results. The gradual shifts in moral philosophy and HPS, accompanied by social and scientific changes have led to a broader social contract between science and society, in which scientists are endowed with the responsibility to uphold, promote and preserve fundamental human interests. The presentation of these responsibilities within life science ethics has been considerably influenced by the international nature of the human rights discourse, as well as the principalist focus of bioethics. Together they have shaped the current promotion of a "global scientific ethics" to guide the behaviour of scientists around the world.

This promotion of a "global scientific ethics" has also been strengthened by the mid-20<sup>th</sup> century rise in sociological studies which critically examined

fundamental aspects of the scientific process in attempts to understand identify common principles by which science was run (Douglas 2007). The work Robert Merton and similar studies in the 1940s attempted to identify the normative and other institutional arrangements that would enable science to exist and function efficiently to allow for unbiased scientific research (Merton 1973, Collins 1983). In his seminal book *The Sociology of* Science, Merton proposed a set of norms (Mertonian norms) that he took to be both the goals and methods of science. These norms, which he proposed distinguished science from politics and other disciplines, included communalism, universalism, disinteredness and organised scepticism (Merton 1973).

Together with the endorsement of a "global scientific ethics" described above, Mertonian norms have been influential in promoting the notion of commonality between scientific communities. Together, these two positions have been highly influential in promoting a view of life science ethics that is both overarching and globally applicable. Such an approach, of course, comes with some important consequences, including a tendency to overemphasise the similarities between scientific communities and detract discussion away from the contextual differences that require examination.

Although such a position has proven extremely influential in life science ethics, it is not without controversy. Indeed, within the broader field of ethics the notion of a "global, secular ethics" is increasingly being scrutinised – and such an approach for life science ethics should be no different. In the following section some of these hesitations are examined in greater detail and related to the current situation in life science ethics.

#### 1.1.2. The Problems of Ignoring Contextuality

It is thus interesting to examine at this point why many systems of global ethics – scientific, medical, legal or pedagogical – are increasingly facing criticism for

problems relating to contextuality. Many scholars, including Alasdair MacIntyre and H. Tristram Engelhardt, have emphasized that achieving a global bioethics is hampered in modern secular societies by the absence of an overriding moral force such as God to objectively determine "good" from "bad" (MacIntyre 1984, Engelhardt Jr 1985). They suggest that there can be no secular moral agreement on any substantive bioethical issues. As H. Tristram Engelhardt suggests, this is caused: "[w]hen the God's-eye perspective is lost, morality is disconnected from a sociohistorically unconditioned reality, as well as from a supposedly canonical rationality, as would be provided by a God's-eye perspective. Morality and bioethics can no longer be held to reflect reality as it is in itself, but rather as it is articulated within sociohistorically conditioned perspectives. Morality and bioethics become cultural creations. As cultural creations, morality and bioethics are in principle intractably plural" (Engelhardt 2011: 247). This, such authors suggest, is largely due to the inability to standardize how moralities diverge in terms of how they regard the good, the right and the virtuous (Engelhardt 2011: 250).

Engelhardt proposes that: ".. because all moralities and bioethics may be concerned with the good it does not follow that all moralities share the same understanding of the good" (Engelhardt 2011: 251). Similarly, such considerations can be extended to include scientific ethics. If, as MacIntyre and Engelhardt propose, the notion of a globally-applicable bioethics is unlikely due to the difficulties discussed above, is it any less likely that such a system can be achieved for scientific research? If a "global scientific ethics" is in fact an untenable position, life science ethics necessarily needs to consider the possibility not only of cultural variations within the global scientific community, but also how their prioritisation of "goods" within their research may alter their interpretation of ethical issues.

Such a position, of course, relies on the observation that scientists on a global level cannot be considered a homogenous community, but rather need to be recognised as a plethora of different communities with varying customs and values. Thus, at this stage it must be noted that the literature is by no means

devoid of discussion on contextual variations between scientific communities. Although the Mertonian norms continue to retain a position in research ethics discussions, after decades of focus on the structural-functional analysis of scientific ethics, the sociology of the scientific community gradually lost ground to attempts to develop a sociology of scientific knowledge and extensive ethnographic studies of particular scientific laboratories (Latour 1986, Mitcham 2003). Studies on the increasingly complicated relationship between science, society and "knowledge economies" highlighted the heterogeneity of scientific communities around the world (such as Traweek 1988). Indeed, as will be further discussed in chapters five and six, the social construction of research communities and the public priorities reflected in differences within funding allocation, research topic preference and public endorsement of research - all of which have had significant influences on the wide variety of research styles around the world. Thus, the hesitations regarding the feasibility of a global ethics for scientific research appear to be endorsed by the existing recognition of the heterogeneity of scientific communities. So why, it is important to ask, does contextuality not play a greater part in current ethical discussions?

Clues as to the answer of this question, I propose, lie in three different areas: the lack of interdisciplinary research in scientific ethics which would take into account the significant amount of sociological work done on contextual variations within the laboratories; the predominance of research ethics (which is discussed in detail below); and the influence of discussions on scientific legislation on those regarding contextual variations. Indeed, in many areas the discussions on contextual variations between research communities focus almost exclusively on regulatory and legislative differences and similarities.

Notwithstanding the prioritisation of free and open research<sup>5</sup> by the global scientific community, many countries have comprehensive (and increasing)

<sup>&</sup>lt;sup>5</sup> It is widely acknowledged that: "for centuries scientists have relied on each other, on the selfcorrecting mechanisms intrinsic to the nature of science, and on the traditions of their community to safeguard the integrity of the research process" NAS (1992). Responsible Science: Ensuring the Integrity of the Research Process (Volume 1). Washington DC, National Acadmies Press.

systems of legislation for many aspects of scientific research, and the variations between these systems is the subject of considerable ethical discussion. This is particularly true for topics such as stem-cell research and genomics. Indeed, these discussions often form the bulk of the references to contextual differences in scientific ethics, which has a number of important implications. Firstly, of course, it focuses ethical discussions on a specific aspect of contextuality within scientific research and thus detracts from other areas such as variations in the social and physical research environments around the world (and consequentially their influence on the ethical behaviour of scientists). Secondly, this focus often means that there is poor elucidation between the distinct types of responsibility that are normally employed in ethical discussions, including causal, legal and moral (Honderich 2005: 815)<sup>6</sup> – something which has the propensity to significantly complicate subsequent discussions on responsibility.

Thus, although the predominant form of responsibility discussed within scientific research tends to be moral responsibility<sup>7</sup>, and focuses on defining and guiding good behaviour, legal responsibility is rapidly emerging as a significant element in these discussions. Although legal and moral responsibilities have a close,

<sup>.</sup> Science has (and continues to have) traditionally had a very low level of official legislation governing its practices. Scientists place a high premium on self-governance and self-surveillance.

<sup>&</sup>lt;sup>6</sup> Causal responsibility, as the name suggests, involves the subject, either directly or indirectly, bringing a certain state of affairs to pass. Legal responsibility is to fulfil the requirements for accountability under the law. Finally, moral responsibility covers (i) having a moral obligation towards a certain action, or (ii) fulfilling the criteria for deserving blame or praise for a morally significant act or omission Honderich, T., Ed. (2005). <u>The Oxford Guide: Philosophy</u>. Oxford, Oxford University Press.

These three states of responsibility are often intricately linked, although the connections between them are not necessary ones. The validity and usefulness of these three states of responsibility are continually being evaluated, and have proven significant challenges for philosophy.

<sup>&</sup>lt;sup>7</sup> In Western philosophy theories of moral responsibility can be dated back to Aristotle (384 – 323 BC), who examined the underpinnings of human virtues and vices in his *Nicomachean Ethics*. Subsequently, Aristotle's theory has been interpreted in (at least) two divergent manners: the merit-based view which accords praise or blame based on merit (as promoted by St Augustine, and Immanuel Kant), and the consequentialist view which accords praise of blame depending on whether the achievement of a desired consequence (as endorsed by Thomas Hobbes, David Hume and John Stuart Mill)<sup>7</sup>. To date there remains little consensus on how exactly to define the concept of moral responsibility, despite its importance in many fields of philosophy.

and often symbiotic relationship, it must nonetheless be noted that a failure to elucidate between these two types of responsibility has the potential to significantly complicate discussions on the subject. Thus, although these recent discussions on variations of legal responsibilities of scientists in different contexts are an important topic, they cannot be taken to also represent the possible variations in moral responsibilities that would be experienced in differing contexts. Attention to this differentiation will be further examined in chapter four.

Acknowledging contextuality in scientific research, while recognised on sociological and legal fronts, thus still tends to need further examination in scientific ethics. Despite the hesitations that I have enumerated regarding the feasibility of a "global scientific ethics", much of the current discourse suggests that this approach is being enthusiastically endorsed. To my mind this leaves a strange situation in which the ethics presented to scientific communities and has the potential to influence how scientists conduct their research; how they view themselves as a collective; and how they interact with society(ies).

Nonetheless, as I proposed above, the lack of explicit discussions about contextuality within scientific ethics can largely be traced to the predominant influence that research ethics has over scientific ethics and the usual manner in which contextual variations are dealt with in this field. In the following section I propose to expand on this (possibly contentious) suggestion by tracing the development of research ethics as a highly influential aspect of scientific ethics. I will then go on to explain exactly why I suggest that contextuality is not often explicitly dealt with in research ethics. Finally, after examining what I call the "RCR model of ethics pedagogy", I discuss how responsibility is conveyed to scientists using this model.

#### 1.2. Internal Responsibilities: Research Ethics

By far, the majority of discussions on responsibility in science tend to focus on the internal responsibilities that scientists have to their research and the research community. Of particular importance for these discussions is the question of how scientists should conduct research in a socially responsive manner while upholding the processes of scientific enquiry such as openness and freedom of research. This focus has led to the development of the field of research ethics which addresses issues relating to experimental design and the implementation of research, including misconduct and whistle-blowing, as well as related topics such as research involving human or animal subjects, the regulation of research and intellectual property of data (Resnik 2011).

Research ethics, no doubt due to the strong influence of bioethics and medical ethics, has developed a strong principalist approach and may be said to promote the notion of a "global scientific ethics". Despite the hesitations mentioned above, however, this continues to be an effective means of developing, promoting and mediating responsible conduct amongst scientists. This section aims to interrogate why this should be the case, and what effect this has had on discussions about responsibilities for scientists.

#### 1.2.1. Research Ethics: an Influential Force in Research

Research ethics is generally understood to focus on the application of fundamental ethical principles to a variety of topics within scientific research. It has been most developed in relation to medical research, and thus bears a strong affiliation to the principalist approach promoted in bioethics. Furthermore, key agreements such as the 1974 Declaration of Helsinki and the earlier 1947 Nuremberg Code have been very important in its development and have pushed human rights to the fore of discussions. In recent decades, however, it has been expanded to include a number of other important areas

other than human experimentation, including animal experimentation, academic conduct and misconduct, and regulation of research (Shamoo 2009).

Research ethics is often presented as a means of delineating the professional norms of behaviour for scientists (Resnik 1998, Shamoo 2009), and prescribing how scientists should behave. In a similar manner to other professions<sup>8</sup>, it aims to provide a platform for discussing the responsibilities of scientists, and a means of holding them publicly accountable for their actions. Similarly to bioethics, these norms are often presented as a series of ethical principles which should be justifiable from a theoretical and intuitive point of view, and thus valued and upheld by researchers in their daily practices (Shamoo 2009: 19)<sup>9</sup>.

What principles constitute research ethics has been the subject of considerable debate, however a number of core traits are regularly identified for individual scientists, including honesty, openness, fairness, truthfulness, accuracy, conscientiousness, giving due credit, respect, collaboration, loyalty, professional quality and whistle-blowing (SCRES 2001)<sup>10</sup>. All of these traits, if acted upon by individual scientists, are believed to be able to strengthen integrity in research, and thus contribute towards responsible scientific research. Many of the principles, thus, promote social responsibility and the public's support of science (Schrader-Frechette 1994, Shamoo 2009).

In this way research ethics may be said to take into consideration the internal responsibilities of the science community towards ensuring the perpetuation of scientific research, promoting cooperation, collaboration and trust among researchers, and assisting in developing the process of scientific research

<sup>&</sup>lt;sup>8</sup> A profession is understood to be more than an occupation – it is a career or vocation with some common social and moral characteristics.

<sup>&</sup>lt;sup>9</sup> Providing that they do not conflict with other principles - if the principles conflict in a practical decision it is generally up to the scientist to use ethical reasoning to settle the conflict.

<sup>&</sup>lt;sup>10</sup> In 2001 the Standing Committee for Responsibility and Ethics in Science (SCRES) reviewed 115 ethical standards for science, representing 23 countries on 6 continents and effectively summarised these core traits.

(Shamoo 2009: 19). Furthermore, research ethics also integrates other important areas such as social responsibility, human rights, animal welfare, and compliance with the law and health and safety that, if ignored, will result in considerable harm for human and animal subjects, students and the public<sup>11</sup>.

Although research ethics has predominantly focused on individual behaviour and ethical conduct, there is a growing awareness of the importance of addressing ethical problems at the institutional level. Research institutions thus have ethical and legal obligations and policies that can either foster or hinder integrity in research (Shamoo 2009: 21), and are beginning to have an increasing number of responsibilities to not only prevent scientific misconduct but also to promote research integrity through the integration of scientific norms into work practices, and the development of regulations that defend and encourage good behaviour (IoM 2002, Fink 2003, Hansen 2006).

Widespread agreement of the approach of research ethics towards subjects such as human and animal experimentation (for example) has resulted in a near-global endorsement of the underlying deontological structure that delineates a number of global maxims. Thus, a more global approach to ethical discussions tends to work well in research ethics and does not hamper international debates regarding correct behaviour for scientists. It is my opinion that this can be related to two different characteristics of research ethics.

Firstly, it could be considered largely due to the widespread agreement regarding particularly what counts as scientific misconduct. In addition to the near unanimous endorsement of human rights and the protection of human subjects in research, there is a global rejection of misconduct that has come to be termed FFP (falsification, fabrication and plagiarism). Thus, while scientists in different contexts might go about fulfilling their research ethics obligations in slightly different manners, there is widespread agreement regarding the

<sup>&</sup>lt;sup>11</sup> This was the subject of two surveys that investigated the subscription to these norms amongst science communities. See Anderson 1994 and Anderson 2000.

deontological rules set out by the ethical system (and the appearance of a global system of research ethics).

Secondly, research ethics has come to have a pervasive influence in the governance of scientific research. Many of the principles of research ethics have informed institutional regulations and national legislation thus shifting the moral responsibilities prescribed by research ethics to scientists into legal ones. In this manner, the moral issues of contextuality (as referred to above) become legal issues and thus form a separate area of discussion. For instance, differences (or discrepancies) in the manner in which human research standards<sup>12</sup> are implemented in different countries often form the underpin many of the current discussions on the subject, such as informed consent and minimum standard of care.

These two issues have also influenced the manner in which responsibilities are discussed in research ethics. The similarities of the expectations placed on scientists regardless of the context in which they conduct their research (such as not to mistreat human subjects, for example), and the close link between moral responsibilities and legal ones have resulted in the assumption of a set of globally-applicable responsibilities that are increasingly becoming legislated. Because of this, it is possible that the introduction of the concept of "role responsibilities" into this discussion might be a helpful means of elaborating on this situation, to better describe how responsibilities are portrayed in research ethics.

<sup>&</sup>lt;sup>12</sup> A review of the differences in international human research standards was compiled by the Office for Human Research Protections (US Department of Health and Human Services). The 2013 report International Compilation of Human Research Standards is available from www.hhs.gov/phrp/international/intlcompilation/intlcomp2013.pdf.pdf

### 1.2.2. <u>Role Responsibilities: a Useful Alternative Method of</u> <u>Discussing Responsibility</u>

The notion of role responsibilities emerged from legal studies, and was first introduced by H. L. A. Hart. It refers to the specific duties attached to a distinctive place or office in a social organisation (Hart 2008: 212)<sup>13</sup>. These duties provide for the welfare of others, or in some way advance the aims or purposes of the organisation and the individual is said to be responsible for the performance of these duties, or for doing what is necessary to fulfil them (Hart 2008: 212). Hart suggested that: "what distinguishes those duties of a role which are singled out as responsibilities is that they are duties of a relatively complex or extensive kind, defining a "sphere of responsibility" requiring care and attention over a protracted period of time, while short-lived duties of a very simple kind, to do or not to do some specific act on a particular occasion, are not termed responsibilities" (Hart 2008: 213)<sup>14</sup>. A responsible person is thus one who is disposed to take his duties seriously, to think about them, and to make serious efforts to fulfil them. Failure to fulfil these ascribed duties may expose the role-holder to censure that may be of a moral or legal kind. Thus, when a person occupies a distinctive place in a social organisation, to which specific duties are attached, he is said to be responsible for the performance of these duties, or doing what is necessary to fulfil them<sup>15</sup>.

<sup>&</sup>lt;sup>13</sup> Although Hart formalised the concept of role responsibilities, the idea can be traced back to ancient Greek philosophy (such as Plato's Republic) and Christian philosophy (as the nature of being a Christian is defined by certain roles).

<sup>&</sup>lt;sup>14</sup> Hart uses the example of a private soldier detailed to keep the camp clan and tidy for the general's visit of inspection. This is his sphere of responsibility, and he is accountable for it. On the other than, if merely told to remove a piece of paper from the approaching general's path, this would be at most his duty (Hart, 2008: 213).

<sup>&</sup>lt;sup>15</sup> Role responsibility within other ethical discussions has lost some of its potency due to the recognition of the variations in societal expectations and context in which the responsibilities are carried out. The recognition of the contingency of social roles, however, has led to a gradual migration away from role responsibilities towards principles in general ethics. The two dominant ethical theories in Western ethics, consequentialism (judging actions in terms of their capacities for good results) and deontologism (judging in terms of the formal properties of the actions in relation to independently justifiable rules), both emphasise the primacy of principles over roles Mitcham, C. (2003). "Co-responsibility for research integrity." <u>Science and Engineering Ethics</u> **9**: 273 - 290.

The concept of a role therefore refers to a social position that combines both descriptive and normative elements. In addition it provides discussions on ethics with an alternative method of confronting the issue of contextuality and relativism, by focusing on the social construction of the responsibilities. In the case of a research scientist, role responsibilities can be taken to refer not only to what is expected of the scientist by society and their peers, but also to prescribe how the scientist should behave to fulfil these obligations (Mitcham 2003).

The concept of role responsibilities, I propose, offers valuable insights into research ethics and the manner in which contextual differences are mediated within international research ethics discussions. The emergence of the multiple layers of national, institutional and informal regulation from governments, funding bodies, journals and other stakeholders in science have resulted in elaborate regulatory environments which govern and control the scientific process, and provide role responsibilities for scientists. Thus, role responsibilities define not only what it means to be a scientist, but also what determines the community as a whole (Mitcham 2003). By referring to role responsibilities (in comparison to traditional deontological duties), it is possible to denote the societal, legal, and institutional expectations that fall onto a scientist with regard to a specific issue.

How these role responsibilities are developed from the ethical principles identified in research ethics is a complicated discussion, involving economic, political, social, cultural and religious aspects. However, despite the myriad of ways in which role responsibilities could be developed for research ethics, it must be noted that this possible heterogeneity is often under-examined. It is likely that this occurs for a number of different reasons. Firstly, the widespread endorsement for the principles enshrined by research ethics and the seemingly clear manner in which they can often be implemented in daily practices (especially in areas such as research misconduct) means that role responsibilities in different communities are often very similar. Secondly, research ethics has predominantly been developed in certain developed

countries (such as the UK and the USA), which have key similarities in certain legislative and cultural areas (particularly with regard to human subject research). Thus, the role responsibilities arising in these countries may be more similar than could otherwise be expected. Finally, due to the prominence of the American model of Responsible Conduct of Research (RCR) in research ethics, these role responsibilities are often assumed to be more standardized than otherwise could be expected. In the coming section the "RCR model" is examined in closer detail, with particular reference to its influence on ethics pedagogy.

This section delineated what I find to be some important considerations regarding the issue of contextuality in research ethics. Over and above any hesitations that one might feel about the notion of a "global scientific ethics" it cannot be denied that research ethics presents a largely unified presence in areas such as scientific misconduct, human and animal experimentation and others. This, as I suggest, is due to the focus of this area and the widespread agreement of the behavioural patterns that it endorses and condemns. Furthermore, by shifting much of the discussion on contextual differences to legal and regulatory debates, it further presents a more unified ethical front than would otherwise be expected.

Research ethics, I feel, benefits greatly from the use of the concept of role responsibilities that address the expectations placed on scientists by virtue of their role as a scientist. Role responsibilities thus straddle the middle ground between moral, legal and causal responsibilities and reflect societal expectations on a particular profession. Within research ethics these role responsibilities are very similar between scientific communities due to the widespread agreement discussed above. However, how research ethics and the accompanying role responsibilities are introduced to daily research and taught to scientists is by no means a simple task. In the next section the American approach to research ethics is discussed in more detail, which will serve subsequently as a model of research ethics pedagogy and engagement.
# 1.3. Responsible Conduct of Research (RCR): a Model of Research Ethics in Action

Within the USA, the increasing social criticism of science in the 1970s and 80s, was associated with rising awareness of scientific fraud and misconduct in research – including falsification, fabrication and plagiarism (FFP) of data, theft of ideas, as well as the abuse of human or animal subjects. This critical attitude continues to be perpetuated by the regular emergence of instances of misconduct in the scientific community, which contributed to the on-going and widespread concern and undermines public confidence in the research process. In reaction to these issues, the need for scientific accountability has become a serious topic for the media, the government and the public (Shamoo 2009). This concern led to the codification of research ethics and its integration into national and institutional regulations - a movement which has become known as RCR - has been firmly established since the 1990s.

In a similar fashion to the general research ethics approach discussed in 1.2, the RCR model has been strongly influenced by bioethical principalism, and promotes the notion of globally applicable and intelligible ethical norms to govern scientific research. This approach has led the RCR model to become associated with specific approaches to responsibility distribution, collective responsibility and regulation of research, all of which are discussed below. As a model for research ethics engagement, RCR has been highly influential in the development of approaches to research ethics pedagogy and awareness-raising initiatives, not only within the USA, but also on a global level.

This section aims to clearly elaborate on what could be termed "the RCR model of ethics education". By clearly defining certain aspects of this model it is hoped that the rest of the chapter will be able to show how such an approach, while well suited to research ethics, loses some of its potency for discussing broad social issues.

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#### 1.3.1. The Focus of RCR

RCR, as a system of research ethics, attempts to address most areas of professional activity that make up a research career. These areas of influence include issues relating to collaborative science research; conflicts of interest and commitments; data acquisition, management, sharing and ownership; human research protection, laboratory animal welfare; mentoring; peer review; publication practices and responsible authorship; and research misconduct (Shamoo 2009). In addressing these issues, the RCR models favours an "assisted responsibility" approach, in which the autonomy of scientists to deal with these issues is mediated by federal agencies, and informed by many US government statues, regulations and policies.

Within this assisted responsibility approach the Office of Research Integrity (ORI) and the National Institute of Health (NIH) have played roles of paramount importance and have contributed significantly towards the development of the federal approach to RCR. Ultimately the federal regulations clearly demarcate behavioural guidelines for scientists, and provide a baseline of acceptable behaviour within research. In many cases these combine a moral obligation with a formalised legal obligation. These regulations have been further endorsed in a number of key publications, such as the National Academy of Science's (NAS) *On Being a Scientist: Responsible Conduct in Research* (NAS 2009). Thus, the RCR model endorses role responsibilities that include accepting and endorsing regulations and legislation.

All RCR guidelines emphasise the importance of ethical conduct on *all levels* of scientific research, advocating for scientific research to be viewed as a collective endeavour. Shamoo and Resnik, in their 2009 book *Responsible Conduct of Research*, elaborate on this approach, saying: *"[t]here is a growing recognition among scientists, government officials, and research institutions that ethical conduct is an important part of research. Ethical conduct is important in research because science is a cooperative enterprise that takes* 

place within a social context. Modern science can be viewed as a profession akin to medicine or law. Standards of conduct in research play a key role in advancing the goals of science; in promoting cooperation, collaboration, and trust among researchers' and in attaining the public's trust and support" (Shamoo 2009: 3). Thus, RCR clearly promotes the view of science as a profession that needs to accept responsibility for upholding certain standards of behaviour.

In the RCR model a level of institutional cooperation is assumed, as research institutions are required by law to have policies that cover various aspects of their research programs if they accept federal funding (Steneck 2007: 12). These include having committees to review human and animal research, processes for investigating research misconduct, facilities for administering research budgets, and adequate enforcement of laboratory biosafety rules and practices for the responsible use of hazardous substances in research. They must also provide training for researchers who will be involved with animal or human subjects (and in particular those on NIH grants). In order to assist research institutions in dealing with research allegations the ORI issued a set of guidelines, however, as institutional policies must encompass the full range of institutional responsibilities, institutional policies are often more comprehensive and detailed (Steneck 2007).

Thus, the RCR model represents an approach to scientific research in which responsibility for research is distributed between the government, research institutions and scientists, and in which collective responsibility is achieved by *everyone doing their bit.* In doing so, the RCR model employs a notion of collective responsibility in its simplest form – as an aggregate phenomenon in which the collective action is a sum of the individual actions. Responsibility is thus distributed between all members of the group<sup>16</sup>, and promotes the idea that the efforts of each person involved in science to conduct research responsibly

<sup>&</sup>lt;sup>16</sup> While such an understanding of collective responsibility of course makes sense, it has increasingly been found to be wanting when more complex actions and groups are being analysed. This will be discussed in some detail in chapter five.

and to produce methodologically coherent research will indeed lead to responsible science on a global level.

It must be noted that this approach is particularly effective in part due to the predominant emphasis that the RCR model places on avoiding misconduct. In the 2007 Introduction to the Responsible Conduct of Research, the author emphasises that "responsible conduct in research is simply good citizenship applied to professional life. Researchers who report their work honestly, accurately, efficiently, and objectively are on the right road when it comes to responsible conduct. Anyone who is dishonest, knowingly reports inaccurate results, waste funds, or allows personal bias to influence scientific findings is not" (Steneck 2007: xi). A "good citizen" is thus portrayed as someone who avoids misbehaviour by following the prescribed norms of behaviour. This emphasis on preventing misbehaviour is highly influential, and reflects the RCR priority to find guidelines for the conduct of scientists. In turn, this echoes what Nicholas Christakis has suggested is bias in American bioethics towards "an expectation that a final and transcendent resolution of ethical disputes is indeed possible" (Christakis 1992). In this manner, the benefits of robust, ethically sound research are the rewards of good conduct, and good conduct is achieved by following the prescribed norms of behaviour.

The combined efforts of the ORI, the government and the scientific community have shaped RCR into a distinctive field that emphasises: honestly, accuracy, integrity, efficiency and objectivity within scientific research. This is achieved by strongly delineating the focus of RCR and the role responsibilities expected of the scientists and research institutions. Nonetheless, it must be noted that most texts on RCR recognise that there is no universal method that applies to all scientific investigations. Indeed, *"[a]ccepted practices for the responsible conduct of research can and do vary from discipline to discipline and even from laboratory to laboratory"* (Steneck 2007: 2), however these variations are rarely explicitly discussed unless misconduct occurs.

In the RCR model a particular emphasis is placed on the importance of educating all levels of science practitioners – including "*principle investigators, postdoctoral students, graduate students, technicians, and staff*" (Shamoo 2009: viii). In achieving this aim, the ORI plays an important role in overseeing and directing research integrity on behalf of the Secretary of Health Services and the American public<sup>17</sup>. It receives considerable Federal funding which is primarily directed to the biomedical and behavioural sciences activities to enhance education in RCR. In these activities, the RCR topics are usually presented as a combination of federal regulations, definitions and policies; institutional policies; and training or case studies (Steneck 2007). These educational approaches are discussed below.

### 1.3.2. Teaching RCR

Despite a widespread commitment to education, adequately equipping scientists in the field of RCR has been associated with a number of problems which have been summarized accordingly: "[g]uidance for the responsible conduct of research is not ... well organized. Some responsible practices are defined through law and institutional policies that must be followed. Others are set out in non-binding codes and guidelines that should be followed. Still other responsible practices are commonly accepted by most researchers but not written down. Instead they are transmitted informally through mentoring, based on the understandings and values of each mentor. This situation is further complicated by the fact that researchers are not routinely tested on their knowledge of responsible practices or licensed. Moreover, their behaviour as researchers is inconsistently monitored and the penalties for irresponsible behaviour vary considerably" (Steneck 2007: 5). Thus, as RCR education involves integrating requirements from professional codes, government regulations, institutional policies and personal convictions (Steneck 2007: 6), developing and rolling-out educational initiatives is far from simple.

<sup>&</sup>lt;sup>17</sup> This is taken from the ORI website.

As discussed above, the primary focus of RCR is research misconduct, and how it can be avoided. What is termed as "misconduct" can of course be debated, however one working definition from the Office of Science and Technology Policy (OSTP) refers to research misconduct as *"fabrication, falsification or plagiarism* (FFP) *in proposing, performing or reviewing research, or in reporting research results*"<sup>18</sup>. The elucidation of these FFP behaviours sets a minimum standard for wrong behaviour. While the identification of FFP behaviours does not imply that all other behaviour is acceptable, it aims to provide a definition of fundamental unacceptable behaviour *specific to scientific research*.

It is assumed that the primary responsibility for reporting and investigating allegations of misconduct belongs to researchers and research institutions (Steneck 2007: 22). This is consistent with the underlying belief that researchers should be allowed to regulate their own conduct. For this system to be effective, individual scientists thus have to take misconduct seriously and understand their responsibilities towards their own actions and those of others. Nonetheless, research institutions are also required to have procedures in place for receiving and investigating reports of research misconduct. They should offer basic protection to researchers raising concerns as well as have procedures in place to deal with the allegations.

In this manner, a considerable amount of RCR education involves describing to scientists the role responsibilities attributed to them in each of the fields of influence. Educational initiatives introduce scientists to their legal responsibilities determined by federal law, and the institutional regulations (which are also often subject to legal oversight), their moral responsibilities based on the norms described above, and those pertaining to the "social

<sup>&</sup>lt;sup>18</sup> This definition also sets a legal threshold for proving misconduct: fabrication is making up data or results and recording or reporting them, falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record, plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, research misconduct does not include differences of opinion.

http://ori.hhs.gov/policies/fed\_research\_miscondcut.shtml (accessed 13/03/2013).

contract" that science has with the American public to uphold their ethical standards and further their social priorities.

In introducing these role responsibilities, RCR training often makes considerable use of case studies as a pedagogical tool. In these case studies students and researchers are presented with cases which illustrate ethical dilemmas, and are required to elaborate on decisions of conduct (Steneck 2007: xii). However, while the efficacy of interactive learning is well documented (Bryant 2003), there have nonetheless been a number of concerns voiced over the years that the overuse of case studies may present students with hypothetical situations which do not reflect the context in which they work. It has been observed that many educational initiatives often rely on the assessment of students' reactions to hypothetical situations, or their understanding of ethical principles, policies or rules. How these modules are able to affect scientists' behaviour remains an area for future research (Anderson 2007)<sup>19</sup>.

Thus, RCR instruction focuses predominantly on the role responsibilities relating to topics associated with the production of scientific knowledge. As these role responsibilities have been the product of the negotiations between science and society, these role responsibilities are enshrined in legislation, institutional regulations and behavioural codes, all of which form an important part of RCR education. As mentioned above, the focus of RCR education is strongly bounded by the emphasis on responsible research, and the ethical principles underpinning it are similarly focused<sup>20</sup>.

<sup>&</sup>lt;sup>19</sup> Furthermore, an emphasis on "solving" case studies reflects a trend in Northern American bioethics towards finding "solutions" for ethical dilemmas (refs), which may provide students with unrealistic expectations. As suggested by Broad and Wade, "*in the acquisition of knowledge, scientists are not guided by logic and objectivity alone, but also by such non-rational factors as rhetoric, propaganda and personal prejudices. Scientists do not depend solely on rational thought, and have no monopoly on it" Broad, W., Wade, N. (1983). <u>Betrayers of Truth:</u> Fraud and Deceit in the Halls of Science. London, Cetury Publishing.* 

<sup>&</sup>lt;sup>20</sup> By this, as will be intensively discussed in chapter four, I mean that the ethical principles underpinning RCR discussions are focused on the objective of guiding behavior away from

Interestingly, due to this focus, and the common aims and outcomes expected of responsible research, RCR education is largely able to transcend boundaries of nationality and discipline and has become a major driving force in research ethics. Indeed, in many instances<sup>21</sup>, a knowledge of RCR is a prerequisite for modern research, as is evidenced by the growing number of online courses and information websites.

### 1.3.3. Other Modes of Ethical Engagement Advocated by RCR

Within the growing culture of research ethics professional scientific societies are starting to play an important role in defining the behavioural norms of their members. Many professional societies, such as the American Association of Microbiologists, have developed codes of conduct for their members that reiterate the principles of research ethics discussed above. The development of such codes of conduct for the life sciences is relatively new in comparison with other fields (such as medicine or engineering), but has received considerable support from the international science community in recent years. In particular, increasing concerns about the new and emerging ethical aspects of biomedical research, and its potential for abuse, have led to a surge of attempts to translate ethical debates into codes (Scholze 2006). While the term *code of conduct* functions as a generic phrase for a number of different types of codes, all of them are united by their attempts to set expectations regarding behaviour for those associated with the life sciences (Rappert 2007).

Codes of conduct commonly include the research ethics norms discussed above: beneficence, non-maleficence, integrity, responsibility and autonomy. Related to this, they explicitly endorse the openness of scientific research and the importance of communality, emphasizing the enduring importance of

misconduct. Thus, for example, the principle of non-maleficence is equitable to avoiding misconduct in research.

<sup>&</sup>lt;sup>21</sup> The NIH, for example, requires all grant holders to have completed an RCR course.

Mertonian norms in the ethos of scientific research. Through the formalization of the implicit principles within science it is hoped that codes will assist scientists in dealing or recognizing tension between the norms discussed above, as well as providing a framework for discussing externally and internally applied pressures that influence these norms (Jones 2007).

Despite the enthusiasm with which codes have been embraced, their implementation has not been without serious complications. In particular, although codifying pertinent ethical principles is an important means of raising awareness, there must be the recognition that such initiatives can only have limited use without concurrent enterprises aimed at developing ethical competence<sup>22</sup> amongst the scientific community. The difficulties of teaching ethics as a separate topic in RCR modules - or as stand-alone courses - means that most scientists may be left under-equipped to deal with complicated ethical Although in recent years improving ethical awareness within the issues. international scientific community through education has recently received considerable international support and endorsement (Mancini 2008, Rappert 2010), amongst the life science community it continues to be patchy and unstandardized (NRC 2011). This is in part due to the challenges associated with developing and implementing education for scientists, including lack of financial support, lack of expertise, and lack of space in the current curricula (NRC 2011).

While codes can provide an important tool for ethics education amongst the science population (Rappert 2007) through which the role responsibilities required of scientists can be put into perspective, the limits of their usefulness needs continued close examination. Currently, it is often the case that the ethical principles enshrined in the codes are often not widely discussed – either formally during education or informally in laboratories, leaving only a tenuous link between them and the role responsibilities expected of scientists on a daily

<sup>&</sup>lt;sup>22</sup> This involves individuals being able to critically assess situations and offer a set of reasons or evidence in support of a conclusion COMEST (2003). The Teaching of Ethics. Paris, France, UNESCO.

basis. In observing this it is important to highlight the differentiation between *understanding* a code of conduct, and *upholding* one. Nonetheless, it must be noted that with the clearly defined role responsibilities for many of the areas of RCR influence, such codes of conduct often prove a useful tool for raising ethical awareness.

Thus, codes of conduct may only reach maximum effectiveness in research cultures which support and nurture ethical behaviour. The assumption that the principles set out in codes of conduct and ethics education are upheld and reinforced by the mentoring structure that characterises modern science is commonly made in discussions on RCR. "Teaching through example" was, and remains, the most common method of ethical supervision (NRC 2011: 5), despite its obvious problems<sup>23</sup> (Anderson 2007). This responsibility is generally placed on the principle investigator (PI), who has obligations to review data, assess reproducibility of results, and to audit and quality control procedures (Wright 2008).

In the USA, the supervision of students occurs within a structured environment of regulation, in which the student and mentor have a contract of duties expected of them (IoM, 2002). Within the duties of the supervisor, it is assumed that they will transmit the national, funding and institutional requirements of the working place, as well as ensuring that these requirements are upheld during daily research. In this they are often supported by institutional structures and research ethics committees (REC)<sup>24</sup> which are tasked to oversee the ethical viability of research proposals.

<sup>&</sup>lt;sup>23</sup> Supervising and mentoring involve a personal relationship between supervisor and student, the norms of which are ill defined and significantly culturally dependent. Furthermore, such relationships depend heavily on the personalities of both supervisor and student, and therefore should be viewed as unique.
<sup>24</sup> Within these environments, the RECs play an important role. There has been considerable

<sup>&</sup>lt;sup>24</sup> Within these environments, the RECs play an important role. There has been considerable discussion regarding the role and focus of these committees, however, at their minimum RECs are required to reconcile research proposals to the institutional, national and international ethical requirements and ensuring that the relevant ethical considerations of the research proposals have been adequately dealt with Douglas, T. M. (2007). "Ethics committees and the legality of research." Journal of Medical Ethics **33**: 732 - 736.

Despite the logic and tradition underpinning personal supervision and ethical development, the limits of this approach have yet to be clearly demarcated. The considerable research into scientific misconduct and the regular reports of such events occurring within scientific research all suggest that research supervision and research environments cannot be uniformly supposed to adequately address ethical development of scientists and their responsible conduct. This is an important point that should be considered in all ethical discussions.

### 1.3.4. The "RCR Model for Ethical Engagement"

The American approach to research ethics as embodied by the RCR model has been highly influential on a global level, and provides an approach of identifying role responsibilities of scientists through integrating the codes, rules, legislation, and policies developed by institutions, processional associations, government agencies and international bodies (IoM 2002, Shamoo 2009). The RCR model is an effective way of breaking down responsibility and integrity within research, as it effectively integrates the ethical and legal requirements to allow researchers to operate efficiently within their context. It is distinguished by a number of different issues:

- Because of the majority of RCR focuses on the process of scientific research, there is a considerable emphasis on the deontological duties of scientists, which are translated into role responsibilities by national and institutional guidelines. Thus, scientists have a clear set of duties that will enable them to conduct research responsibly.
- RCR focuses on specific areas of research, such as misconduct. Thus, the ethical principles underpinning RCR discussions and enshrined in codes of conduct refer to specific behavioural issues within the clearly defined context of research ethics. This often means that ethical discussions can transcend national borders without any contextual

difficulties. In turn, this provides the impression of the existence of a global scientific ethics.

- A strong emphasis on FFP misconduct as led to a "minimum standard of responsibility" being identified. In many cases, unless explicitly addressed, "good conduct" is often equated to the absence of misconduct.
- The emphasis of integration of scientist, research institute and national regulatory framework is vital to the description of individual responsibilities, and the existence of a functional research environment is assumed in RCR discussions.
- The distribution of responsibilities amongst the different partners of RCR not only results in clear set of responsibilities for the individual scientist (associated with duty), but also a vision of collective responsibility as an aggregate phenomenon in which every element "plays its part" to ensure a broad sense of responsible science.

The RCR model thus presents a specific manner of approaching ethical engagement amongst scientists. While not explicitly endorsing principalism (Mitcham 2003) and the notion of a global ethics, the clearly defined end goals (such as minimising research misconduct) are so widely understood and endorsed that ethical principles are routinely associated with similar role responsibilities in many different contexts. This, in my opinion, gives a slightly misleading impression of the presence of a "global research ethics". A further consideration in relation to these goals is that the RCR model often promotes the *absence of misconduct*. This is further stressed by the emphasis on *everyone doing their part* towards collectively responsible conduct in research.

While, as I mentioned above, this approach is well suited to research ethics engagement, it is also possible that such an approach will not be as successful for raising awareness of broad social issues in science. Nonetheless, because of the current poor state of ethics education for scientists on an international level (Mancini 2008) it is often only through research ethics courses that scientists get any ethical training (if at all). Thus, broader social issues are often incorporated into RCR training and within RCR-focused assessments (such as on funding forms).

It is my opinion, however, that the characteristics of the RCR model may complicate attempts to engage scientists in broad social debates. The following section will examine these broad social issues and the ethical requirements that exist for dealing with them in some detail. It will then attempt to clearly define some of the difficulties associated with raising awareness for these issues, and where the RCR model may be poorly suited to deal with these situations.

### 1.4 Social Responsibility and Broader Social Issues

In the concluding discussion of *On Being a Scientist: a Guide to Responsible Conduct in Research* it was observed that "the consequences of discoveries in basic research are virtually impossible to foresee" (NAS 2009: 20), and that scientists have to be prepared to deal with the questions that are raised by relating "scientific knowledge to society in such a way that members of the public can make an informed decision about the relevance of research" (NAS 2009: 21). This brief section emphasised an emerging concern in the life science: how scientists and the public can create a negotiated understanding of how scientific research is shaping and altering society. Thus, it points to some broad social issues that necessitate careful consideration about the impact and long-term consequences of conducting certain avenues of research.

In the last decade the scientific and biotechnological advances, such as "Dolly the sheep" the human genome project, human embryonic stem cells, gene transfer, transgenic animals, and the chimera hu-mouse have all raised serious concerns about the knowledge generated by the life sciences, while also offering significant opportunities for advancement (Jones 2007). These emerging technologies are challenging human imagination, and the speed of

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modern scientific research has made it difficult for ethics to catch up. Increasingly, questions are being asked about the limits of scientific research – whether there is in fact some knowledge better left untouched. Science, together with associated fields such as computing, is increasingly called upon to defend and redefine their social contract with society. In addressing this, the integrity and responsibility of scientists necessarily extends beyond simply conducting credible research within an established social institution, but should also include critical reflection on what is the right thing to do for (and with) society (Mitcham 2003).

Many of these broad social issues have become the focus of considerable ethical, legal and social debates. Indeed, issues such as stem cell research have raised such attention that they have influenced legislation governing scientific research. Nonetheless, despite their considerable presence in public and legal discussions, these issues are rarely formally broached as part of scientists' education. As noted above, as the bulk of ethics education occurs in the form of RCR, and if these subjects are raised at all, it is usually in relation to RCR (or as case studies to discuss RCR principles).

Although "any education is better than no education", it must be questioned whether the RCR model discussed above is well suited to this type of ethical engagement. Specifically, and relating to the points discussed in 1.3.4, is the strong focus on role responsibilities for the individual scientist, the view of collective responsibilities as an aggregate phenomenon, and the low emphasis on contextual differences between research cultures suitable for adequately engaging with these issues? Furthermore, it is important to question whether promoting the impression of a "global secular ethics" within such issues presents a significant barrier towards building capacity on an international level.

This section will critically examine the possibility of scientific responsibility for these broad societal issues, in order to then contrast them to the image of responsibility commonly presented in research ethics and RCR. It will do so using two different angles: firstly whether scientists should take responsibility for these issues, and secondly what responsibilities should they be allocated? In using this approach, I will also attempt to question whether, when dealing with such issues, the notion of a global scientific ethical approach can be forwarded. I will then assess whether the current methods of teaching responsibility in scientific ethics (such as the RCR model) present barriers to, rather than avenues for, developing an international community of responsibility and awareness. I will then suggest some areas that may present particular challenges to understanding responsibility for these issues, and propose manners in which these problems could be mitigated.

# 1.4.1 Should Scientists Take Responsibility for These Issues?

The first question that needs to be considered when talking about broad social issues and science is whether it is feasible to expect scientists – individual or collective – to take responsibility for these issues. In doing so, the recent trend towards socially constructed knowledge discussed in 1.1 is emphasised and marks a significant step away from empiricist interpretations that separated the scientist from the downstream applications of his work. Nonetheless, even using a more social constructivist approach, it is important to understand exactly why scientists can be taken as (at least partially) responsible for the broader applications of their research.

As mentioned above, modern notions of responsibility beyond the laboratory have their roots in the Baconian ideal of science oriented so as to contribute to the lot of humanity and its progress (Bacon 1887: 242). This idea of science benefiting humanity has evolved over the centuries<sup>25</sup> and remains a prevalent attitude towards modern scientific research. The commitment of the scientific community to this idea forms the basis of the pact between science and society,

<sup>&</sup>lt;sup>25</sup> Indeed, earlier framings of this commitment were rather paternalistic in that the scientists were largely responsible for determining what would benefit society, and in what way. The gradual evolution of socially robust science has led to socially negotiated definitions of beneficence.

and in so doing binds the scientific community to some form of responsibility for these broader societal issues.

Thus, the idea that scientists are in some way complicit in responsibility for the duty towards beneficence for humanity is not new. How this is responsibility is framed, however, has evolved over the centuries. In contrast to Bacon's emphasis of man's "power over nature", a new approach has emerged in which the philosophy of Hans Jonas is particularly influential. Instead of endorsing the belief that the unprecedented powers of modern technology will lead humanity towards a utopian ideal, Jonas instead suggests that modern progress is leading humanity towards global ecological and human disaster (Jonas 1979, Donnelley 1989). In order to adequately confront this, Jonas demands that we renounce utopian dreams, and instead exercise a new responsibility commensurate with our novel powers (Donnelley 1989: 636). From Jonas' point of view, therefore, we cannot accept that all knowledge will lead towards a brighter future, but require considerable caution in furthering scientific advances.

Although the recognition of the ecological and moral crisis facing humanity is not unique to Jonas' philosophy, what does distinguish his writing was his recognition that traditional systems of ethics do not adequately make provision for the rapidly expanding fields of science and technology. In his seminal book *The Imperative of Responsibility: In Search of an Ethics for the Technological Age*, Jonas proposes a new ethics of responsibility in an attempt to establish practical obligations in the face of technological power and potential ecological disaster.

Jonas's position is founded on his rejection of the prevailing theory of scientific materialism. At the heart of materialist theories of nature is the thesis of causal determinism, where nature is considered a self-sufficient and closed system. Although this is a useful for claims on scientific knowledge, it becomes

problematic when the materialist thesis is taken as defining the bedrock of reality, and thus underpinning metaphysics.

Such a position leads to considerable inconsistencies as, by this definition, materialism must eliminate subjectivity. However, this cannot be, and in some way the materialist must preserve the phenomena of our subjective life. Jonas argues that the reality and potency of the subjectivity is not incompatible with "deterministic" science if the latter is stripped of its metaphysical pretensions (Donnelley 1989). Instead, he suggests returning human subjectivity to its self-validating credentials, while also emphasising the interdependency of mind and body. Furthermore, he emphasises that "*we know and must take seriously the now incontrovertible fact that all organic life has evolved out of and remains within nature*" (Jonas 1979: 66, Donnelley 1989: 644).

By weaving together the fates of man and nature, Jonas presented a revolutionary angle to moral philosophy. Most fundamentally, nature is rehabilitated as a significant realm of existence (Donnelley 1989: 645), and in itself harbours overall value and specific concrete values<sup>26</sup> as well as an inherent vulnerability. This places humans under an obligation of responsibility to the valuable and vulnerable others. Thus, when it comes to moral responsibility, we have no choice but to care (Jonas 1979: 134), and, in a time of rapidly expanding technology, we are ethically obligated to take care and be cautious (Jonas 1979: 38).

This call to worldly virtue is an important contribution to ethics, and together with the concept of "metaphysical guilt" proposed by Karl Jaspers have come to form the bedrock of many discussions on these broader societal issues (Hansen 2005, Hansen 2006: 73). In his book *The Question of German Guilt*, Jaspers distinguishes between moral guilt that is based on what one does, and moral guilt based on who one is (Jaspers 1961). This metaphysical guilt, as he calls

<sup>&</sup>lt;sup>26</sup> In contrast to the materialist view of nature, which is inherently valueless. This leads to Jonas violating two cardinal principles of modern philosophy: there can be no metaphysical truth, and no "ought" derived from what "is" (Donnolley, 1989: 649).

the latter, is distributed to all members of a community who stand by while their fellows produce harm. Thus, to be morally blameworthy is connected to belonging to an evil community, and not necessarily to the causal involvement in the action. In the case of the broad social issues relating to science, scientists can be seen to possess responsibility due to who they are as scientists, and not necessarily what they have personally done.

In turn, the concepts of global responsibility and metaphysical guilt have significantly challenged discussions on collective responsibility, as they emphasise the individual's relation to their community's harmful actions. This emphasis has led to a number of different philosophers, including Larry May and Juha Raikka, to propose alternative theories of collective responsibility that will be discussed at length further in this thesis. Briefly, they emphasise that "seeing one's own moral status as interrelated to that of one's fellow group members will negate the tendency to ignore the most serious moral evils: those which can only be thwarted by the collective efforts of the community" (May 1987: 253)<sup>27</sup>.

Using the work of Jonas and Jaspers it is possible to construct a case for by which scientists should be held responsible for the broad social issues arising from their work. This global sense of responsibility, it can be proposed, exists by virtue of scientists' roles as scientists and cannot be ignored. Nonetheless, how scientists are responsible and for what remain difficult questions. In particular it is important to note that by virtue of broad social issues arising from the social contract between scientists and society, the issue of contextuality becomes a prominent consideration.

<sup>&</sup>lt;sup>27</sup> Many others philosophers, have criticised the notion of metaphysical guilt as it severs the link between responsibility and control, while also violating the Rawlsian concept of "separateness of persons" which underpins many modern concepts of justice (http://plato.stanford/edu/entries/collective-responsibility/ (Accessed 03/08/2012).

# 1.4.2 Incorporating the Issue of Global Responsibility Within Life Science Ethics

Although the issue of global responsibility places all scientists under a firm obligation to care, it is nonetheless a very difficult concept to practically address in ethical discourse. How exactly such a responsibility should be conceptualised and acted upon are, understandably, very difficult issues to deconstruct. Nonetheless, in this area these problems are influenced by two important considerations. Firstly, that the "metaphysical guilt" alluded to by Jaspers and subsequent authors suggests that *communities* of scientists and their collective actions will play an important role in discussing broad social responsibilities. Secondly, as broad social issues are a result of the social contract between scientists in a specific context and the general public, how these issues are prioritised, interpreted and dealt with can vary considerably around the world.

Thus, while these broad social issues are internationally applicable due to the global responsibility of scientists, the manner in which this responsibility is acted upon within a specific research context has the potential to differ quite considerably due to variations in the social contracts between scientists and the general public. This raises two important points for consideration for ethics discussions. Firstly, as much of current ethics discourse tends to downplay contextual variations between research communities (as discussed above), will it be able to adequately deal with the need for considerable contextually-informed discussion on variations between research communities? Secondly, will the potential problems associated with the promotion of a "global science ethics" be sidestepped in a similar fashion to research ethics, or will it cause considerable complications in international debates?

By and large, attempts to raise awareness of broad social issues occur on institutional or national levels, with the assumption that increasing education will foster the eventual development of a culture of global responsibility.

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Nonetheless, the majority of the contact that scientists have with these broad social issues remains through public debates, newly emerging legislation, or through the social impact elements on funding application forms – and not via formal educational modules. Indeed, such modules are largely lacking, and within classrooms these issues mainly form an "add-on" section of research ethics training – often as case studies to debate research ethics issues.

It is my belief that aligning the promotion of responsibility for broad social issues with responsibility for research ethics has the potential to significantly complicate educational matters, as the different approaches to responsibility, if not explicitly addressed, may cause significant problems for learners. Indeed, the difficulty of breaking down the notion of "global responsibility" in a meaningful manner together with the clearly defined areas of responsibility in research ethics may lead to considerable confusion. Some of these hesitations are detailed in the table below, which contrasts the use of the RCR model in research ethics education to using it for raising awareness of broad social issues.

Characteristic of RCR model	Impact on RCR training	Possible problems associated
		with using the RCR model for
		raising awareness of broad
		social issues
Appeared promotion of global	Similarities between research	The importance of the social
ethics	environments and goals	contract between science and
	minimises contextual variation	society makes it unlikely that
	in the interpretation of ethical	issues of contextuality can be
	principles.	sidestepped.
Promotion of role	Clearly defined goals and	Promotion of a "global sense
<u>responsibilities</u>	reasonably similar societal	of responsibility" difficult to
	expectations make the	break down into role
	delineation of role	responsibilities.
	responsibilities useful.	
Strong emphasis on	Absence of misconduct is	How a global sense of
<u>"minimum standard of</u>	roughly equal to misconduct.	responsibility is acted on is by
responsibility"		no means clear. Indeed,

		identifying a "minimum
		standard of responsibility" for
		these issues is of debatable
		utility.
Collective responsibility	The presence of an integrated	How a collective "global
distributed as an aggregate	system of ethics, regulations	responsibility" is interpreted
	and legislations distributes	and acted on is not clear.
	responsibilities and promotes	
	an aggregate collective	
	responsibility.	
Applicable to wide range of	Similar goals and expected	Discussions largely context
<u>contexts</u>	outcomes	dependent
Assumption of a certain	Similarity of goals and	Importance of considering the
degree of homogeneity	expected outcomes minimises	nuances of each scientific
between scientific	differences between	community and the society in
<u>communities</u>	environments	which it is embedded

<u>Figure 1.</u> Comparative table detailing the differences between using the RCR approach to teach research ethics or awareness of broad social issues.

If broad social issues are presented using the RCR model, or alongside research ethics issues, it would thus seem likely that considerable confusion could arise regarding the responsibilities that scientists have for broad social issues. In addition to the complications compared above, one must consider exactly how a scientist will access the diffuse concept of a "global responsibility" when also faced with the concrete role responsibilities of RCR. Will such a seemingly nebulous concept be able to hold up against the scientist's many responsibilities as: "policy-maker, public advocate, as well as the traditional roles of teacher, researcher, and independent practitioner" (Mitcham 2003)?

Furthermore, in contrast to the specific responsibilities associated with one's personal work that are presented as part of RCR, engaging with broad social issues requires having a well-informed overview of the subject matter at hand. As mentioned by Mitcham: *"[s]ubjectively, being buried in the trenches of highly specialised research projects makes it difficult to identify broad trends.* 

Objectively, blindness is reinforced by the manifest complexity of a world in which science and technology merge into what is sometimes called technoscience, and the contested relations between technoscience and human affairs" (Mitcham 2003: 279).

All in all, it is possible that using an RCR approach to teach awareness of broad social issues may have some significant (and perhaps unrecognised) implications for the success of any initiative. Presenting these broad social issues in a manner in which scientists identify not only their responsibility towards them but also their agency for influencing them is a difficult task perhaps made more difficult by the RCR approach.

While these considerations are important for all communities of scientists, the boom in life science research in developing countries – and in particular the newly industrialized countries such as India, Brazil, South Africa and China (BRICS countries) – have further broadened the variety of contexts under which science is done. In such countries where there is not a long history of scientific research, mirrored by often lacking governmental regulation and support structures (Masanza 2010), these considerations become particularly pertinent.

In many cases the only ethics education that these scientists receive is RCR education imported wholesale from developed countries such as the USA. Thus, while already dealing with the problems above, these scientists also have to access the underlying cultural assumptions implicit within the ethics. In particular, the lack of sensitivity to the possibility of varying content of ethical principles, a bureaucratisation and role responsibility distribution for these issues, and a lack of discussion regarding the influence of context on the development of these issues all become potentially problematic. These, in turn,

contribute to difficulties in encouraging individual and collective responsibility for these problems amongst the scientific community<sup>28</sup>.

Of course these are theoretical speculations based an analysis of current trends in scientific ethics. Thus, it is possible to question whether such speculation actually reflects situations within laboratories around the world. It therefore becomes apparent that such speculation will be significantly informed by the generation and analysis of empirical data gathered from representative laboratories. This approach was adopted in this thesis, and the research plan is briefly detailed below so as to provide a framing for the rest of the analysis.

# 1.5 Developing a Research Plan

This chapter has thus outlined some of the problems that I perceive to be associated with teaching broad social issues to scientists using an RCR model of engagement, and the possible barriers that this may unnecessarily hinder the building global cultures of responsibility and awareness. The rest of this thesis will be concerned with empirically examining these issues using the concept of dual-use as a "case study" example of a broad social issue. This concept is examined in some depth in chapter two. Chapters three to six detail the extended fieldwork that I conducted in a number of laboratories in developing (South Africa, Kenya, Uganda) and developed countries (UK). This fieldwork allowed me to empirically examine the theoretical issues identified above, and

<sup>&</sup>lt;sup>28</sup> Agencies dealing with cases of scientific misconduct, such as the US Office of Research Integrity and the German Research Foundation (DFG) continue to perpetuate the assumption that misconduct is a problem at the level of the individual Franzen, M., Rodder, S., Weingart, P. (2007). "Fraud: causes and culprits as perceived by science and the media." <u>EMBO Reports</u> **1**: 3 - 7.

<sup>,</sup> and this focus on the individual and not on the environment has made its way into ethical discussions as well. However, although misconduct in such situations could easily be attributed to "bad apples" within the scientific community, refocusing on contextuality as a means for minimizing the effects of a stressful/imperfect environment may prove fruitful for all discussions Kumar, M. N. (2010). "A theoretical comparison of the models of prevention of research misconduct." Accountability in Research **17**(2): 51 - 66.

<sup>,</sup> Resnik, D. B. (2011) What is ethics in research and why is it important? http://www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

in particular to critically study whether current approaches to raising awareness of dual-use issues have the potential to cause misunderstandings amongst scientific communities when too closely related to RCR issues such as biosafety and biosecurity. Furthermore, it emphasised that these difficulties are exacerbated in developing countries. In the data analysis, the thesis will examine these issues under three subheadings that are briefly introduced below.

#### 1.5.1 The Content of Ethical Principles

Broad societal issues are necessarily concerned with bioethical norms such as beneficence, non-maleficence, autonomy, and justice. Although within approaches such as principalism, these norms are attributed a globally-applicable definition, there have been many criticisms of such an approach (as by Engelhardt Jr 1986). Increasingly it is being suggested that the content associated with ethical principles is dependent on the cultural context in which they are applied. If this is accepted, it would thus appear that between different national contexts the same ethical principles may refer to differing contents. Not only does this suggestion seriously conflict with the idealised notion of a "global science ethics", but it also raises considerable questions regarding how such variations in content can be acknowledged and mediated in international discussions.

Thus, particularly with broad social issues, it is important to question far the content of ethical principles (what it denotes within a specific culture) can be expected to transmit between cultures? Without lapsing into ethical relativism, how can the contextual specificity be upheld without sacrificing the possibility of international harmonisation and cross-border dialogues? These issues are examined in chapter four. In particular, the chapter questions how and why the content of ethical principles within these broad social debates is rarely closely interrogated. As this problem is exacerbated when one considers transmitting elements of a broad social debate wholesale to another culture – particularly

one not traditionally identified as Western, a comparison is made between scientists in a developed country (UK) and developing countries (South Africa, Kenya and Uganda).

It is possible that by interrogating the content of these ethical principles as well as the assumptions regularly made when transmitting these broad societal concerns across borders, that a more comprehensive approach to building capacity in these areas may be achieved. By drawing attention to the differences between the content prescribed to culturally informed versions of ethical principles it may be possible not only to avoid misunderstandings, but also to build policies that more adequately reflect the concerns of scientific communities.

### 1.5.2 Systemic Issues in Research and Collective Responsibilities

As discussed above, the RCR model of ethical engagement is premised on a comprehensive system of institutional and legal regulation, and one of its primary foci is to educate scientists about their role responsibilities within such a context. Within such an environment role responsibilities provide a valuable way of illustrating to scientists how they integrate within the larger regulatory-physical environment, what their expected behaviour should be – and particularly the minimum standards of conduct that will be tolerated.

Of course, because the RCR model was developed within the USA, it relies on a typically Western interpretation of the laboratory structure, the existence of institutional and national regulatory structures and extra-laboratory infrastructures in its elaboration of role responsibilities. Furthermore, because such an environment *will be there* in most American laboratories, it is rarely explicitly mentioned in ethical discussions. Furthermore, in many cases, other developed countries have successfully adapted the RCR model because a similar physical and regulatory infrastructure *is already in place*. Thus, within much RCR-related discourse, the regulatory-physical environment receives little explicit attention, and the existence of many elements are assumed, including:

- Adequate waste disposal
- Adequate and efficient border controls
- Adequate core funding for laboratory essentials
- Adequate power, internet and communication within work environments
- Adequate laboratory support, including maintenance of machines
- A regulatory and legislative environment which governs most practical aspects of research

Nonetheless, as discussed above, for many laboratories in developing countries RCR instruction through online modules and funding obligations remains the sole point of ethical education for scientists. Within these laboratories the existence of a comprehensive regulatory-physical environment cannot be taken for granted, and many experience considerable systemic problems during daily research.

In chapter five these issues are examined in closer detail, particularly whether introducing Western-centric role responsibilities as defined ethical obligations to developing country scientists has the potential to cause considerable ethical discomfort. Thus, the chapter questions whether being unable to fulfil role responsibilities due to systemic issues (rather than ethical motivation) affects the integration of scientists into a broader culture of ethical responsibility.

# 1.5.3 Building Communities of Responsibility

Within the RCR model of ethical engagement, the traditional hierarchical structure of Western science, and the emphasis on learning *in situ* within the laboratory plays an important role. This is generally assumed to include a hierarchy of mentorship from the head of department (HoD) and PIs, through

the research scientists and postdoctoral scientists to the students and technicians (IoM 2002). Within this model, the PI plays a fundamental role in not only creating an ethical culture in which to work, but ensuring that ethical principles are adequately transmitted and implemented within their group (IoM 2002).

In modern societies, it has been noted, *"science is institutionalised, and the term science includes institutions, networks, and other social aspects associated with the production of scientific knowledge"* (Hess 1995: 1). The rise of the sociological study of scientific research has led to some excellent studies that examine the structure of scientific laboratories. While sociologists such as Latour focused on the social factors that formed an integral part of routine scientific procedure, in which the material context is a vital element in knowledge construction (Latour 1986: 21). Others such as Traweek<sup>29</sup> and Haraway<sup>30</sup> conducted comparative studies between disciplinarily related research groups in different countries. These studies played an important role in emphasising cultural differences between laboratories – further dispelling the idea of cultural and methodological unity amongst the international science population. Indeed, these national styles of research appear to be remarkably resilient to globalisation, and often coincide with national differences in the social structure of research organisations (Hess 1995: 145).

<sup>&</sup>lt;sup>29</sup> In her book *Beamtimes and Lifetimes,* the anthropologist Sharon Traweek examined contrasts between Japanese and US scientists working in physics. She showed how differences in funding structures affected the formation of a cadre of experienced, highly trained technicians which ultimately affected the manner of research being done in each institution. Traweek, S. (1988). <u>Beamtimes and Lifetimes</u>. Cambridge, Massachusetts, Harvard University Press.

<sup>&</sup>lt;sup>30</sup> Another interesting example can be taken from primatology by examining the differences in research methodologies and outcomes based on differences in Asian and Western cultures. While Westerners tend to view a sharp division between nature and culture, Japanese tend towards nature as something to be cultivated by human hand, and the animal/human relationship in terms of a family metaphor in which animals are humans' younger siblings. This has led to differences in research focus and the development of alternative theories. Haraway, D. (1992). "The biopolitics of a multicultural field." <u>GENDAI-SHISO revue de la pensee</u> d'aujourd'hui 20 **10**: 108 - 147.

In chapter six the limits of an RCR interpretation of *in situ* learning is examined in relation to developing awareness for broad social issues. The chapter questions whether an implicit reliance on the mentorship of the PI and other superiors is an adequate means of developing an ethically aware culture within laboratories. Furthermore, as laboratories in developing countries often operate within different organisational parameters, it is possible that this RCR-focus exacerbates the problem of raising awareness.

However, before these themes are dealt with in any detail it is necessary to introduce the concept of dual-use, which has been used as a focalising example of a broad social issue. In chapter two, dual-use is examined in some detail, with particular attention being paid to current dual-use awareness-raising initiatives.

# 2. The Dual-Use Dilemma in the Life Sciences

Chapter one outlined some of the difficulties associated with fitting broad social issues into the current modes of ethical engagement in the life sciences. In particular, it examined how the strong focus on the possibility of a "global science ethics" coupled with a deontological approach and the clear definition of role responsibilities - as exemplified in the RCR model – presented a number of issues when used to engage scientists in broad social discussions (discussed in section 1.5). In particular, the chapter questioned whether the promotion of "globally-applicable" instead of "contextually-informed" principles, a lack of explicit discussion on variations in the regulatory-physical research environments, and an implicit assumption of a social structure of laboratories could cause considerable ethical confusion and distress amongst scientists. Furthermore, it speculated that this could be particularly pertinent in developing countries where the research environments vary considerably from those in the West.

This chapter further examines this conundrum, using the topical concept of dual-use as a focalising example of a broad social issue in the life sciences. Broadly, this concept refers to the possibility that potentially beneficial scientific knowledge may be misused by a third party for nefarious purposes (Miller 2007). In the wake of the events of 2001, dual-use has rapidly become a topic of considerable discussion within many stakeholder communities associated with the life sciences. Increasingly, this concept is raising questions regarding the limits of research, the control of research, accountability within research, and of course responsibility for any dual-use events.

Dual-use, as the potential to turn the "life sciences into the death sciences" (Rappert 2007), raises many ethical questions relating to how and why harm is conceived in a particular manner, how responsibility is meted out for nefarious events, and what in fact constitutes adequate care to avoid events that are (at best) only a future potential. In particular, relating to scientists, dual-use forces

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us to question whether scientists should be held responsible for the misuse of their research at all, and if so what exactly can be expected of them to prevent such occurrences. Nonetheless, despite these difficulties, it is generally accepted that scientists should identify with a "global responsibility" for addressing these issues and assisting in ameliorating the potential within the life sciences.

Dual-use ethics dealing with these issues remains relatively small, and a considerable amount of the dual-use debate has been shaped by policy-related initiatives from the USA and the UK. This heritage, understandably, has shaped the dual-use debate both in its focus and approach to ethics. In particular, ethical discussions tend to promote a principalist approach, and often include dual-use in broader RCR discussions on biosafety and biosecurity ("biorisk") (IoM 2002). Thus, dual-use ethical discussions often tend to favour of the promotion of a "global dual-use bioethics", and could be viewed as downplaying some issues relating to contextuality that were elaborated on in chapter one. Within dual-use ethics there is, consequentially, considerable focus on developing role responsibilities for scientists to address dual-use control.

The current "RCR focus" of dual-use ethics necessitates questions regarding whether the approach provides an adequate basis for raising dual-use awareness within *all* scientific communities around the world. This is particularly pertinent when one considers how the notion of a "global responsibility" for dual-use issues is contrasted to the practical role responsibilities of biorisk management. Furthermore, and of particular interest to this thesis, one must question whether the strong Western association of the RCR model is suitable for raising dual-use awareness in non-Western countries. Particularly in relation to developing countries, one must question whether the style, content and assumptions made by these initiatives influences their efficacy within these communities.

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This chapter begins by briefly examining the development of the concept of dual-use, and its incorporation into discussions on the life sciences. It then reviews some of the key reports addressing dual-use issues in the life sciences, and relates this to the emerging characteristics of the dual-use debate. Dual-use control and the issue of responsibility within dual-use are then discussed in some detail, after which dual-use pedagogical initiatives are examined. The chapter ends by critically examining how the current manner in which dual-use is conceptualised and presented to scientists may cause it to fall short of its stated ideal to build a *"common culture of awareness and a shared sense of responsibility within the global community of life scientists"* (NSABB 2006: 5).

# 2.1. <u>The Dual-Use Dilemma and the Life Sciences</u>

While the last century has seen the rapid advances in biotechnology yield great social and economic benefits in the public health, agriculture and energy development sectors around the world (Sture 2010), accruing these benefits has not been without concerns. The growing realisation that peaceful science and technology research also generates risks has engendered much unease. Increasingly, it is being questioned whether there is the possibility that beneficial, well-intentioned research can be applied for destructive purposes such as biowarfare and bioterrorism (NRC 2004).

These concerns are embodied by the concept of dual-use, which refers to the misuse of the knowledge generated by scientific research. By questioning *how, when,* and *to what ends* scientific knowledge can be misapplied after its creation, dual-use forces highly critical analyses of the limits of responsibility in science, and the locus of any such responsibility. Thus, any discussion on dual-use activates speculation on the global responsibility to prevent harm. In this way, the dual-use concept embodies the broad social issues described in the previous chapter, as it requires a negotiated understanding between science and the general public to establish the aims and desired outcomes of scientific research.

Nonetheless, within the field of dual-use ethics, discussions on contextual variations in the understanding of the concept are often downplayed. Instead, these seem to be superseded by discussions on the development of global ethical approach, or contextual variations in legislation of dual-use initiatives. Such observations signal the existence of similarities between current dual-use ethics discussions and research ethics as elaborated on in chapter one.

This section aims to examine why dual-use is often presented in a similar manner to research ethics subjects, and not as a broad social issue. I suggest that this is largely due to the close association between dual-use and biorisk management that has been spearheaded by scholars in the USA. These events will be examined, after which some of the key documents of the dualuse life sciences debate, to highlight their influence over the development of the concept.

### 2.1.1. The Development of the Concept of Dual-Use

Scientific research has always had an ambiguous relationship with beneficence and harm. While the benefits gained from scientific research are undoubtable, the longstanding relationship between scientific research and the military is unequivocal, and over the centuries scientific discoveries have contributed significantly to the art of warfare<sup>31</sup>. The recognition of the dangers posed by military research, and the harms resulting from its applications has caused it to be a closely guarded field, and military research has long been characterized by strict regulations on access and the flow of information (McLeish 2007). This longstanding tradition has influentially compartmentalized the harm arising from military applications of scientific research away from academic (or civilian) science, leaving the harm arising from academic science a rather nebulous concept in most historical discussions.

<sup>&</sup>lt;sup>31</sup> It must be noted that military scientific research is a complicated topic and will not be addressed in this thesis.

Within this broader field of scientific research, the well-established prioritization of openness and freedom of research has characterized most discussions about harm arising from research. In these discussions the possibility of harm caused by research has usually been counteracted by the belief in the ability to minimize it through collective awareness and scrutiny. Thus, the idea of limitations on scientific research is regularly rejected in favour of protecting the maximum level of transparency in all scientific enterprises. Furthermore, the longstanding endorsement of empiricist approaches to ontology (as discussed in chapter one) has contributed towards this stance by emphasizing the disjunction between scientific research and technological applications. Thus, until recently, academic science was characterized by a greater emphasis on the duty of scientists to generate methodologically sound knowledge, rather than their moral responsibility for the later applications of their research.

The changing epistemological landscape of the early 20<sup>th</sup> century<sup>32</sup> away from strictly empirical interpretations of knowledge generation and related discussions the responsibilities of scientists towards their research (discussed in section 1.1) coincided with the emergence of nuclear sciences. Scientists working in the field of nuclear physics prior to the advent of the Second World War recognized that their research, while offering the potential for significant, beneficial civilian applications could also be used for negative effects<sup>33</sup> - concerns that were tragically demonstrated by the development of atomic weaponry and their use in the attacks on the cities of Hiroshima and Nagasaki. This series of events gave rise to considerable consternation within the scientific community, and increasingly scientists began to question their responsibilities towards the knowledge they generated and its downstream applications (Evans 2010). These concerns laid the basis for the modern dual-use debate, characterized by the potential for scientific knowledge with beneficial applications to be misused for disreputable purposes.

 $<sup>^{32}</sup>$  As discussed in section 1.1.

<sup>&</sup>lt;sup>33</sup> The development of the dual-use concept in nuclear sciences has been well examined by Evans, N. G. (2010). Dual-use Bioethics: the Nuclear Connection. <u>Wellcome Trust: Building</u> <u>Sustainable Capacity in Dual-use Bioethics monographs</u>. Bradford, University of Bradford.

As a reaction to the dual-use potential of their research, the nuclear science community developed an approach to information, known as the "born secret" culture, to control all research, materials and personnel (Evans 2010). "Born secret" refers to information being classified from the moment of its inception, usually regardless of where it was created. This position has been very influential in the development of the Atomic Energy Act of 1946, and the subsequent legislation that addresses it. In this manner, the "born secret" model has been highly effective in controlling access to nuclear information, and thus in the development of national security policies.

Although the success of the "born secret" movement within the nuclear sciences has been considerable, the limitations for its applications to other fields of research have long been recognized. In particular, it is acknowledged that its success has been largely dependent on the relatively small field of nuclear sciences and the specialized materials that nuclear research requires<sup>34</sup>. Thus, despite the influential position that nuclear sciences have in the development of the dual-use debate, as a model of dual-use control it has proved incompatible with larger and more generalized fields of research that, in the latter part of the 20<sup>th</sup> century, started to be associated with dual-use concerns.

As the dual-use debate moved beyond the nuclear sciences, so too did the term "dual-use" expand beyond its original civilian/military roots. A review by Atlas and Dando in 2006 noted a number of different formulations that have subsequently been employed. These included how notionally civilian facilities can be used to develop military items; how equipment and materials intended for peaceful purposes can be used for destructive ones; and how the knowledge and techniques generated through science can aid the development

<sup>&</sup>lt;sup>34</sup> This was explicitly mentioned in the Lemon-Relman report of 2006. The report stated that models of control, such as the materials inventories utilized in the nuclear sciences are insufficient to deal with the problems faced by the life sciences. It was noted that the availability and relatively low costs of the reagents necessary for biological research made it unlikely that control could be achieved solely through limiting access or keeping registers for reagent usage (NRC, 2006: 166).

of weaponry (Atlas 2006). These changing interpretations of the dual-use concept can also be seen to reflect an evolving understanding of the relationship between scientific knowledge and its technological functions.

In a comprehensive examination of this issue, McLeish and Nightingale suggest that in earlier discussions on science and technology, technological applications were viewed as being "embedded" within an item of scientific research. Thus, the dual-use potential of an item of research was intrinsic to that research, and dual-use dilemmas were primarily related to preventing inherently dangerous research and technology from getting into hostile hands. In more recent discussions, they propose, the technological applications of research are viewed rather as imposed properties rather than intrinsic ones. Therefore, technological functions are created as a process of evolution involving wider socio-technical systems, and dual-use arises as a result of technological convergence where different downstream technologies share some of their upstream technological inputs (McLeish 2007). This approach challenges the dual-use concept, as it implies that any piece of research has the potential to contribute (in part or in whole) to downstream misuse. Importantly, this nonlinear view takes into account that any technological applications are mediated through social choices and institutions (McLeish 2007).

This brief review of the last century builds a picture of dual-use as a continually evolving concept. From its early inception in the nuclear sciences, the concept has broadened beyond its traditional civilian/military focus to present a more diffuse picture of concern. This widening of focus has in part been due to a changing interpretation of process of technological application, with modern understandings suggesting that *any* research potentially may contribute towards a downstream malicious application. With these changes it is becoming apparent that the presence of dual-use potential in all scientific research needs to be acknowledged, and a global obligation towards responsibility for it.

For such a generalized obligation to become meaningful, however, it must be acknowledged that the concepts of harm and beneficence need to be carefully unpacked. It is only by carefully determining what is interpreted as "harm" and "beneficial research" that the concept of dual-use gains meaning. Thus, if (as suggested in chapter one) one abandons the possibility of a global secular ethics to guide this process, it is necessary that these concepts be regarded as created through context-dependent processes where priorities of both scientists and the society which they serve are collaboratively determined. Similarly, dual-use awareness can be seen as an evolving process mediated through the interactions between scientists and the society in which they conduct their research. However, whether this is adequately acknowledged in dual-use ethics remains a point of contention, which will be discussed later in the chapter.

Before proceeding to these discussions, however, it is necessary to consider the current developments of the dual-use debate specifically within the life sciences. As the majority of this particular dual-use debate has been developed in the UK and USA, the debate has been heavily influenced by this predominantly Western perspective and thus reflects a specific developed country perspective. This observation, in my subsequent critique of current dual-use ethics, will become an important aspect of considerations.

#### 2.1.2 Dual-Use in the Life Sciences: an Evolving Sense of Concern

In recent decades research in the life sciences has made remarkable progress and the boundaries of what is conceived as possible are continually changing. Revolutions in fields such as genetics, synthetic biology, proteomics and related advances in bioinformatics and information processing are presenting a view of a "brave new world" and are potentially poised to yield great benefits to humanity. Nevertheless, these advances have been met with increasing concern, as many critics question whether these disciplines might in fact be
generating knowledge that might *further* – rather than *prevent* – the spread of disease (Bezuidenhout 2012).

In relation to dual-use, these concerns have become focalised in the post-2001 climate of heightened security concerns. The terrorist attacks on the World Trade Centre and the Anthrax attacks have had a significant impact on *how* security concerns are perceived – and *what* exactly constitutes a threat. They have shifted the focus from purely military concerns to the possibility of scientific research being misused by non-state parties in terrorist activities. In particular, the Anthrax attacks (despite being largely a biosecurity issue) highlighted the possibility of the "threat from within" – of the misuse of scientific research by the very people who generate the knowledge.

These concerns have been highly influential in the dual-use discussions within the life sciences, and the concept has come to refer to the potential for any beneficial scientific research to be misused by a third party for nefarious ends (Miller 2007). Within this interpretation, the "third party" commonly refers to non-state actors (such as terrorists or disaffected scientists), and "nefarious ends" to the application of biological knowledge to terror events (NRC 2002).

These modern concerns regarding terrorist attacks, rather than national military projects, have influenced the manner in which dual-use has come to be represented within life sciences debates. Instead of focusing on technologies with civilian and military applications, or technologies that can serve multiple purposes, debates tend to focus predominantly on how emerging knowledge and techniques (as opposed to bioagents and lab equipment) might figure in the development of biological weapons. Thus, within the life sciences, questions on the dual-use potential of research increasingly associated the nefarious misuse of *knowledge* through the development of biological weapons by non-state parties.

Despite this shift in focus from the more traditional definitions of dual-use, the foundations for the dual-use discussions in the life sciences are rooted in the strong historical precedence to support a moratorium on biological weapons. The first fundamental international norm against their use was concretised in the Geneva Protocol in 1925, which, together with the 1972 Biological and Toxic Weapons Convention<sup>35</sup> (BTWC) formed the basis of the modern biological weapons prohibitions regime (Kelle 2006). The BTWC in particular clearly defined an unambiguous norm that completely prohibits the acquisition and use of biological and toxic weapons under any circumstances<sup>36</sup>. Although certain countries abstain from signing the convention, it (together with its periodic reviews) nonetheless created an environment in which no country dares to argue that biological weapons can ever have a legitimate role in national defence<sup>37</sup> (Kahn 2006).

The BTWC, while contributing a moral framework for subsequent discussions on biological weapons, remains an advisory body with no means to enforce controls on the signatory countries (Kelle 2006). Thus, despite the widespread endorsement of the overall principles enshrined in the BTWC, the field of biological weapons security is characterised by an absence of a uniform

<sup>&</sup>lt;sup>35</sup> Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare (signed at Geneva on the 17<sup>th</sup> of June 1925) and the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (signed at London, Moscow and Washington on the 10<sup>th</sup> of April 1972).

<sup>&</sup>lt;sup>36</sup> The BTWC has 8 major articles. These include: (1) Never under any circumstances to acquire or retain biological weapons. (2) To destroy or divert to peaceful purposes biological weapons and associated resources prior to joining. (3) Not to transfer, or in any way assist, encourage or induce anyone else to acquire or retain biological weapons. (4) To take any national measures necessary to implement the provisions of the BWC domestically. (5) To consult bilaterally and multilaterally to solve any problems with the implementation of the BWC. (6) To request the UN Security Council to investigate alleged breaches of the BWC and to comply with its subsequent decisions. (7) To assist States which have been exposed to a danger as a result of a violation of the BWC. (10)To do all of the above in a way that of encourages the peaceful uses biological science and technology. http://www.unog.ch/80256EE600585943/(httpPages)/04FBBDD6315AC720C1257180004B1B2 F?OpenDocument (accessed 08/08/2012).

<sup>&</sup>lt;sup>37</sup> The BTWC makes provision for research for defence purposes. The scope and effect of BTWC-sanctioned research is an area of considerable debate and beyond the scope of this thesis.

approach to bioweapon control, and every country has remained largely autonomously in charge of their development of control initiatives.

Nonetheless, the commitment of the signatories to the common goal has been invaluable in framing the ethical landscape of these discussions. Signatories, by signing the BTWC, have agreed "never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict" (BTWC 1972: article 1). In no uncertain terms, such an obligation clearly defines a commitment to non-maleficence through identifying the means to harm inherent in biological research.

In the decades leading up to 2001, the BTWC influence within beneficial research had been predominantly in awareness raising, and in building capacity in biosafety and biosecurity measures<sup>38</sup>. Despite the Anthrax attacks being predominantly a biosecurity issue, the migration of the dual-use concept into the life sciences rhetoric on threat and harm drew considerable attention to the fact that existing biosafety and biosecurity controls were insufficient to address the possibility of *knowledge* as well as physical samples and materials from being misused. It thus became apparent that further statements on dual-use were needed in order to better understand the threat of dual-use and how mitigating these threats translated into responsibilities for the scientific and security communities.

<sup>&</sup>lt;sup>38</sup> The penetrance of this, however, may of course be debated as ethics education and dual-use awareness remains low within the general scientific community NRC (2011). <u>Challenges and Opportunities for Education about Dual-Use Issues in the Life Sciences</u>. Washington D. C., The National Academies Press.

The recognition of these needs has seen the proliferation of reports dealing with dual-use issues in the life sciences<sup>39</sup>. Arguably the most influential statement was the US National Academies report *Biotechnology Research in an Age of Terrorism* ("The Fink Report". NRC 2004) released in 2003. This, together a subsequent report *Seeking Security: Pathogens, Open Access and Genome Databases* ("The Falkow Report". NRC 2004) and the National Science Advisory Board for Biodefense's (NSABB) *Globalization, Biosecurity, and the Future of the Life Sciences* ("The Lemon-Relman Report". NSABB 2006) have proven very important in defining the subsequent dual-use landscape.

## 2.1.3 Shaping the Dual-Use Landscape in the Life Sciences

The production of the Fink report in late 2003 was a significant event in the emerging discussion on the dual-use and the life sciences. The report declared that its focus was *"the intentional use of biotechnology for destructive purposes"* (NRC 2004: 14 - 15). The committee chairman, Professor Gerald Fink of the Whitehead Institute for Biomedical Research, defined the problem in the following manner:

"... almost all biotechnology in the service of human health can be subverted for misuse by hostile individuals or nations. The major vehicles of bioterrorism, at least in the near term, are likely to be based on materials and techniques that are available throughout the world and are easily acquired. Most importantly, a critical element of our defence against bioterrorism is the accelerated development of biotechnology to advance our ability to detect and cure disease.

<sup>&</sup>lt;sup>39</sup> These include governments and professional communities in science, public health and security, such as the WHO (2007). Scientific Working Group on Life Science Research and Global Health Security: Report of the First Meeting. Geneva, World Health Organization.

<sup>,</sup> the OECD (2007). Best Practice Guidelines on Biosecurity for BRCS, Organization for Economic Cooperation and Development.

and the UN (2008). Report of the Meeting of States Parties, BWC/MSP/2008/5. Geneva, United Nations

have all recognized and promoted the need for preventive and responsive measures to mitigate the potential for misuse of the life sciences Sture, J., Minehata, M. (2010). Dual-use education for life scientists: mapping the current global landscape and developments. <u>Report of the Bradford meeting</u>, July 2010. Bradford, UK, Bradford Disarmament Research Centre.

Since the development of biotechnology is facilitated by the sharing of ideas and materials, open communication offers the best security against bioterrorism. The tension between the spread of technologies that protect us and the spread of technologies that threaten us is the crux of the dilemma" (NRC, 2004: vii).

Thus, in comparison to the BTWC and other preceding documents, the Fink report emphasised the use of biological weapons by terrorist groups, as *bioterrorism*. With this focus in mind, the committee examined their mandate to review the current rules, regulations and institutional arrangements in the USA that provided oversight of research on pathogens and potentially dangerous biotechnology research; to assess the adequacy of these regulations in preventing the destructive application of biotechnology research; and to recommend changes that could improve the USA capacity to prevent the destructive application of biotechnology research, while still enabling legitimate research to be conducted (NRC 2004: 2). In their assessment of their charge, the committee concluded the following:

"[w]ith regard to oversight of research, no country has developed guidelines and practices to address all aspects of biotechnology research. The Committee has concluded that existing domestic and international guidelines and regulations for the conduct of basic or applied genetic engineering research may ensure the physical safety of laboratory workers and the surrounding environment from contact with or exposure to pathogenic agents or "novel" organisms. However, they do not currently address the potential for misuse of the tools, technology, or knowledge base of this research enterprise for offensive military or terrorist purposes. In addition, no national or international review body currently has the legal authority or self-governance responsibility to evaluate a proposed research activity prior to its conduct to determine whether the risks associated with the proposed research, and its potential for misuse, outweigh its potential benefits. The Committee concluded that the existing fragmentary system must be adapted, enhanced, supplemented, and linked to provide a system of oversight that will give confidence that the potential risks of misuse of dual use research are being adequately addressed while enabling vital research to go forward." (NRC 2004: 3).

Thus, misuse of scientific research was divided by the committee into two different areas: (1) the risk that dangerous agents which are the subject of research will be stolen or diverted for malevolent purposes; and (2) the risk that the research results, knowledge, or techniques could facilitate the creation of "novel" pathogens with unique properties or create entirely new classes of threat agents (NRC 2004: 1). In order to address these two different areas of misuse, the report clearly differentiated between existing biosafety and biosecurity practices (relating to the control of the first definition of misuse), and their inadequacy to deal with dual-use concerns (relating to the second definition of misuse). By explicitly recommending the development of further practices specifically designed to address the dual-use potential of life science research the committee positioned dual-use in a realm linked, but not equitable to, safety and security concerns.

To address these issues, the report summarised the committee's findings in seven different recommendations. These were:

- Educating the Scientific Community. The report endorsed national and international professional societies and related organizations and institutions creating programs to educate scientists about the nature of the dual use dilemma in biotechnology and their responsibilities to mitigate its risks.
- 2. Review of Plans for Experiments. The report recommended that the Department of Health and Human Services (DHHS) augment the already established system for review of experiments involving recombinant DNA conducted by the National Institutes of Health to create a review system for seven classes of experiments (the Experiments of Concern) involving microbial agents that raise concerns about their potential for misuse.
- 3. Review at the Publication Stage. It was recommended that selfgovernance be allowed by scientists and scientific journals to review publications for their potential national security risks.

- Creation of a National Science Advisory Board for Biodefense (NSABB). The committee recommended that the DHHS create an advisory board to provide advice, guidance, and leadership for the system of review and oversight proposed.
- 5. Additional Elements for Protection Against Misuse. The committee suggested that the federal government rely on the implementation of current legislation and regulation, with periodic review by the NSABB, to provide protection of biological materials and supervision of personnel working with these materials.
- 6. A Role for the Life Sciences in Efforts to Prevent Bioterrorism and Biowarfare. The committee required the national security and law enforcement communities develop new channels of sustained communication with the life sciences community about how to mitigate the risks of bioterrorism.
- Harmonized International Oversight. It was recommended that international policymaking and scientific communities create an International Forum on Biosecurity to develop and promote harmonized national, regional, and international measures that will provide a counterpart to the system we recommend for the United States. (NRC 2004: 4 - 12).

The Fink report thus influentially shaped the dual-use debate in a number of related areas. Of crucial importance, relating to the nature of the harm arising from the misuse of scientific research, the report - in no uncertain terms – linked it to bioterrorism. This, in turn, led to an emphasis on current biosafety and biosecurity regulations and the need to develop further regulations in order to address this issue. As demonstrated by recommendations two and three, this was concretised into specific outlets for action including review of publications and experimental designs.

Furthermore, the Fink report was highly influential in the manner in which it delineated the types of research from which "concern" could arise. In contrast to broader formulations that identify in the dual-use concept the "potential for any research to contribute towards nefarious effects", the Fink report focused

on specific types of research, which it felt required oversight. As detailed in recommendation two, the committee identified seven classes of experiments that it believed illustrated the types of endeavours or discoveries requiring review and discussion by informed members of the scientific and medical community before they are undertaken or, if carried out, before they are published in full detail. They include experiments that:

- Demonstrate how to render a vaccine ineffective.
- Confer resistance to antibiotics or antivirals.
- Enhance a pathogen's virulence or render a non-pathogen virulent.
- Increase a pathogen's transmissibility.
- Alter a pathogen's host range.
- Enable evasion of diagnostic tests.
- Enable weaponization of pathogens and toxins (NRC 2004: 5).

The classification of these research areas as "experiments of concern" has been highly influential in subsequent discussions on dual-use, and presents a set of demarcated boundaries on which to develop dual-use policies<sup>40</sup> particularly in relation to the publication of information (as will be discussed later). The focus on specific "experiments of concern", rather than science in general, was further underpinned by another NRC report entitled "Seeking Security: Pathogens, Open Access and Genome Databases" ("The Falkow Report". NRC 2004). This report was the product of a committee headed by Stanley Falkow that was mandated to examine the position of genome databases and raw data within dual-use discussions. This report proposed a clear distinction between sequence data and the organism it represented (NRC 2004: 6) and, while advocating the need to regulate access to certain organisms, did not encourage restrictions on genetic (and specifically raw) data<sup>41</sup>. These two reports have been highly influential in demarcating strictly

<sup>&</sup>lt;sup>40</sup> By this I refer to the recognition that *any* research could contribute towards negative ends was viewed as too broad for attempts to practically implement dual-use controls. <sup>41</sup> The report stated that: *"there is no clear demarcation between bioterror-agent genome* 

defined areas of focus for dual-use discussions, as well as the recognisable potential for harm arising from these areas of research have shaped subsequent analyses.

In dealing with the dual-use potential of the life sciences, the committee advocated that (as far as possible) decision-making should be left to the scientific community. In this manner, the report emphasised the importance of freedom of research and autonomy within scientific research – reiterating the importance of minimising the restrictions on modern scientific research. Nonetheless, the committee also recognised the limits of an over-reliance on the scientific community, and advocated the establishment of a national body to advise on policy responses. This model of "assisted autonomy" has proven popular in subsequent models addressing dual-use, and functions as a mediating mechanism between scientific interests and governmental requirements. Acting on the recommendation, the NSABB was established in 2005 to provide advice, guidance and leadership in the US for a system of review and oversight of experiments of concern, and has since proved highly influential in dual-use issues.

In 2006 under the co-chairs Stanley Lemon and David Relman, the NSABB produced a report entitled "*Globalization, Biosecurity and the Future of the Life Sciences*" (commonly known as the Lemon-Relman report). This report was as a result of a mandate to examine the current trends and future objectives of research in the life sciences that may enable the development of a new generation of future biological threats (NSABB 2006: vii). In so doing, the committee attempted to define the research horizon of the next five to ten years and to clarify ways in which dangers to society could be anticipated, identified or mitigated. Thus, in contrast to the Fink and Falkow reports, the Lemon-Relman addressed concerns about how new developments in the life sciences – including how they are intersecting with other rapidly advancing fields such as

sequences and other genome data, genetic expression data, protein structures, and other kinds of research results" (NRC, 2004b: 4). The report concluded that preserving open access and furthering the norm of openness within scientific research was of the utmost importance (NRC, 2004b: 7).

nanotechnology and materials science – may enable the creation and production of wholly new threats of biological origin (NSABB 2006: viii).

In their report, the committee commented on the difficulty with which future predictions about scientific research can be made, and how the task of surveying current technology trends in order to anticipate what new threats may appear in the future will be a continual task (NSABB 2006: viii). It was suggested that while existing paradigms have worked effectively for controlling nuclear arms proliferation, initiatives such as information control, materials inventories and so forth have limited relevance or use in the control of biological weapons proliferation (NSABB 2006: ix). These realisations led the committee to critically examine the strengths and weaknesses of establishing dual-use controls.

Despite the difficulties of anticipating the dual-use threats arising from life science research, the committee emphasised that it was of vital importance that life scientists, and the funding agencies and editors that support their research take "every possible step to ensure that the fruits of their work are not exploited in a malevolent fashion, to the detriment of society" (NSABB 2006: ix). In order to achieve this, those working in the life sciences require a greater appreciation of the dangers associated with their work, and a "greater willingness to shoulder this responsibility" (NSABB 2006: ix).

The committee summarised its findings in five different recommendations:

- 1. The committee endorses and affirms policies and practices that, to the maximum extent possible, promote the free and open exchange of information in the life sciences.
- 2. The committee recommends adopting a broader perspective on the "threat spectrum".
- 3. The committee recommends strengthening and enhancing the scientific and technical expertise within and across the security communities.

- The committee recommends the adoption and promotion of a common culture of awareness and a shared sense of responsibility within the global community of life scientists.
- The committee recommends strengthening the public health infrastructure and existing response and recovery capabilities (NSABB 2006: 159 - 203).

Similarly to the Fink and Falkow reports, the Lemon-Relman report emphasised the counterproductive nature of efforts to control the flow of biological information (NSABB 2006: x). It argued that, given the widening threat spectrum, the best means of future protection was by the exploitation of the very science that is the cause of concern. Thus, almost paradoxically, the committee suggested that the advances in science vital to national security require a robust scientific enterprise, which in turn depends on the free exchange of biological data among scientists (NSABB 2006: x). In order to ensure this open interaction between scientists the committee emphasized the need to regulate these issues around the globe. Importantly, they stated "*it is clear that different societies may have vastly different perspectives on these issues and may adopt divergent paths while aiming to achieve similar goals. To succeed in reducing the threats posed by these advancing technologies will require an appreciation of these differences and an understanding that science does not stop at our borders" (NSABB 2006: x).* 

These observations have been important in the promotion of a "global vision" for dual-use control that emphasises the need for an interdisciplinary and multifaceted approach to control and response. The Lemon-Relman report has been heavily quoted in its endorsement of a "*common culture of awareness and a shared sense of responsibility within the global community of life scientists*" (NSABB, 2006: 5). The report drew attention to the need for support programmes promoting the beneficial uses of technology in developing countries (NSABB 2006: 192), and the need for the establishment of globally distributed, decentralized and adaptive mechanisms with the capacity to deal with the consequences of dual-use events (NSABB 2006: 193). The committee recognized that science is a global enterprise, and with the increasing level of

international collaboration and exchange of information, materials and staff it is vital that this be reflected in any dual-use initiative. Nonetheless, how such a global response to dual-use issues is to be initiated and fostered (as discussed later in the chapter) remains a complicated discussion.

In contrast to the Fink report, the Lemon-Relman report explicitly advocated the widening of the threat spectrum, as it was "doubtful that any authority could enumerate a "select agent list" that [was] sufficiently comprehensive, robust, or of enduring relevance, although most currently listed agents, such as smallpox, [were] likely to remain a potential menace even as new threats emerge" (NSABB 2006: 175). The committee specifically advocated adopting a "a broadened awareness of threats beyond the classical "select agents" and other pathogenic organisms, to include, for example, approaches for disrupting host homeostatic systems and/or the creation of synthetic organisms" (NSABB 2006: 177). This recommendation, thus, extended both the Fink and Falkow reports. In recognising the limitations of the select agent list for dual-use concerns, it emphasised the point made by the Falkow report that the threats of knowledge and physical entity were not always equitable. Moreover, by broadening the threat spectrum of dual-use the Lemon-Relman committee extended the predominantly genomic focus of the previous reports to include new and emerging technologies.

Recommendations three and five recognised the scope of that dual-use events could have on the public, and the need to strengthen ties with the security and public health communities to improve prevention and response measures. The committee explicitly stated that there was no ""silver bullet" capable of providing absolute protection against the malevolent application of new technologies. Rather, [it suggested that] the actions and strategies recommended [in it were] intended to be complementary and synergistic" (NSABB 2006: 161). The report went on to recognise that "an effective system for managing the threats that face society will require a broad array of mutually reinforcing actions in a manner that successfully engages the variety of different communities who share stakes in the outcome" (NSABB 2006: 161). These recommendations

have been highly influential in further conceptualisations of dual-use control, as concretised in the "web of prevention" discussed below.

Together, the Fink and Lemon-Relman reports have significantly shaped the field of dual-use. Although by no means the only reports on dual-use available (many other countries and non-governmental organizations have produced their own literature on the subject), this US-centric approach has come to dominate most discussions and control initiatives. Together, they produced an interpretation of dual-use that may be seen to have the following characteristics:

- The harm associated with dual-use is specifically focused on bioterrorism.
- Dual-use is intrinsically associated with biosafety and biosafety, and forms part of a continuous spectrum of biorisk.
- Dual-use requires a global, interdisciplinary and multifaceted approach to control.
- Any dual-use controls have to explicitly support openness, freedom of research and the maximum amount of autonomy for the scientific community, although a model of assisted autonomy is promoted to help scientists in their responsibilities.

The influence of this approach has, despite the limited number of bioterrorist attacks in the past, and the difficulties experienced by even well-funded groups and states in weaponizing pathogens (Bezuidenhout 2012), caused dual-use discussions within the life sciences to predominantly associate the nefarious misuse of biological research with the actions of sub-state actors, such as terrorist groups. Indeed, notwithstanding the remoteness of sub-state groups successfully making use of advanced life science research, many researchers argue that the disruption and economic cost of any terrorist<sup>42</sup> attempts justifies terming such attacks "successful" or "highly consequential". In addition to

<sup>&</sup>lt;sup>42</sup> For example, the 2001 Anthrax attacks in the USA, while not causing major casualties, caused severe social and economic disruptions.

shaping how the concept of dual-use is discussed, these reports have also been highly influential in focusing the issue of dual-use within the life sciences – and as such defining the locus of concern within these fields of research.

#### 2.1.4 Framing the Dual-Use Issue in the Life Sciences

In many respects, the Fink and Lemon-Relman reports proposed two different approaches to evaluating the dual-use potential of life sciences research. The former emphasised the risk arising from individual research experiments, while the latter promoted a wider focus on the cumulative and iterative potential of science and technology raised by increasing geographically dispersed activities. Despite these significantly differing approaches, however, it has been the Fink approach which has dominated both academic and policy discussions with its proposed list of "experiments of concern" and more narrow focus of scrutiny and action.

In recent years, particularly after the events of 2001, there has been an increasing reliance on a small number of studies as a means of characterising concerns (WHO 2011). These, commonly termed "experiments of concern", represent a few specific research projects that have generated dual-use concerns. One such was the "mousepox experiments" published in 2001. This research was conducted by the Australian National University and CSIRO Sustainable Ecosystems and focused on developing a vaccine that would induce infertility in rodents. The development of such a vaccine would have been highly beneficial to the agricultural community and assist in controlling rodent-related crop destruction (Jackson 2001). Nonetheless, during the research it was discovered that the insertion of the IL-4 gene into the mousepox virus created an extremely virulent strain which was capable of killing vaccinated mice (Jackson 2001). The researchers quickly recognised the possibility that this research could be misapplied using the smallpox virus to create a weaponised virus for use on the human population and proactively drew attention to these possibilities (Selgelid 2010). The recognition of the

threat inherent in this research generated considerable discussion regarding the publication of these data, the release of these data, and the responsibilities of all those involved (Nowak 2001).

This mousepox research has come to be a highly debated "case study" within dual-use discussions. Indeed, this research together with the other commonly used examples such as the chemical synthesis of poliovirus cDNA (Cello 2002) and the resurrection and sequencing of the 1918 Spanish flu virus (Taubenberger 1997), have been highly influential in subsequent dual-use debates and policy development. Focusing on these discrete instances of research fits in well with the conceptual framework established by the reports discussed above, by presenting clear possibilities of harm and misuse. This has significant implications on the development of dual-use ethics, as the focus has necessarily been on analysing and preparing for discrete instances of research. Thus, instead of adopting a broader view of global responsibility, there has instead been an endorsement of what Nicholas Christakis has termed "American solution-driven bioethics" (Christakis, 1992), with a predominant emphasis on problem solving and the identification of solutions.

The trend towards using focusing on individual incidences of research in dualuse discussions has been further underpinned by the actions of the NSABB. One of the central tasks for the NSABB has been to develop recommendations on "guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis of dual-use biological research and research results" (NSABB 2006: 17) for the US federal government. In 2007 the NSABB proposed a split between research which might have some sort of dual-use potential, and that which is "of concern". Thus, in subsequent discussions, the NSABB has used the term "dual-use research" as referring *"in general to legitimate life sciences research that has the potential to yield information that could be misused to threaten public health and safety and other aspects of national security such as agriculture, plants, animals, the environment and material" (NSABB 2007: 16). In contrast, "dual-use research of concern" refers to <i>"the subset of life sciences research with the highest potential for yielding*  knowledge, products, or technology that could be misapplied to threaten public health or other aspects of national security" (NSABB 2007: 16).

This explicit divide between "dual-use research" and "dual-use research of concern" has been very influential in how dual-use responsibilities are conceptualised and distributed. Indeed, this has been particularly obvious in the trend towards "tick box" ethical exercises (NSABB 2007)<sup>43</sup> which often form the principle ethical interactions for researchers not engaged in activities of particular concern. As will be discussed below, this approach creates a very distinctive approach to dual-use ethics and the requirements developed therein.

The approach developed in the USA, as reflected by the Fink, Falkow and Lemon-Relman reports, thus presents a specific interpretation of the dual-use concept that is reflective of the social culture of the country, the political and regulatory environment in which the research takes place, as well as the current trends in American bioethics. This approach, as mentioned before, has been extremely influential in the development of most dual-use discussions internationally, and continues to provide reference points for most research on the subject.

The characteristics discussed above – the focus on preventing harm, the endorsement of the development of dual-use controls, and the close link between dual-use and biorisk management – have also contributed significantly to the development of dual-use ethics and discussions on responsibility. In the next section this will be discussed in further detail and I will attempt to highlight

<sup>&</sup>lt;sup>43</sup> This approach was based on the low identification rate of research "of concern" within journals. The NSABB proposed that the initial review of whether or not the research was "of concern" should be carried out by the senior project leader, who should ask of their work: "... based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or material" (NSABB, 2007: 17). Alternative systems have been proposed, such as the "Biological Research Security System" offered by the Center for International and Security Studies at Maryland, but the NSABB approach has been by far the most influential.

the RCR-focus on dual-use ethics together with the problems I perceive to be associated with this approach.

# 2.2 Developing Dual-Use Ethics

A considerable amount of discussion within the dual-use debate focuses on the need for a global sense of awareness and responsibility for the dual-use potential of the life sciences. In so doing, the dual-use debate recognises the limits of appealing to responsibility on a causal level due to the difficulties associated with assigning responsibility for an event that is, at best, a possible, unintentional future event. Instead, it would appear that these discussions are appealing to a global responsibility similar to that proposed by Jaspers and Jonas and discussed in chapter one. In a way, it may be suggested that by virtue of *being scientists*, the entire science community must assume some level of responsibility for the dual-use potential of their research.

However, despite this appeal towards developing a global responsibility, and no doubt largely due to the heightened climate of security awareness in post-2001 USA, ethical discussions on how a global responsibility for dual-use could be conceptualised have been superceded by practical speculation on how dual-use could be controlled within modern research. This preference towards identifying and developing practical initiatives for control was reflected in the recommendations made in the reports discussed above. Indeed, these reports have been highly influential in shaping discussions on dual-use ethics, due to their prominent position in current dual-use debates, which may be summarised in a number of points.

Firstly, the specific link between the issue of harm arising from research and bioterrorism has placed it firmly on the end of the biosafety/biosecurity risk spectrum (IoM 2002). Secondly, the multi-factoral implications of a dual-use event has led to a recognition that any attempt at dual-use control requires an

interdisciplinary approach involving multiple stakeholders including the security and healthcare communities. This approach emphasises the unlikelihood of the scientific community being able to adequately address the dual-use concerns of their work in isolation. Thirdly, despite the need for multiple actors in dual-use control, the strong commitment to maximising openness, freedom and autonomy has resulted in an emphasis on scientific involvement and the need to build capacity for dual-use awareness within the scientific community.

These issues, together with the emphasis on "experiments of concern" have two important implications for any ethical analysis of dual-use. Firstly, by presenting the concept as a biorisk management issue, the field of dual-use ethics a close association with RCR (as the umbrella field for most discussions on biosafety and biosecurity), and consequentially (in line with my argument in chapter one), is inextricably linked to the notion of a global system of ethics as well as the promotion of identifying role responsibilities for scientists. Secondly, the emphasis on the differentiation between "dual-use research" and "dual-use research of concern", and the continued presence of the "experiments of concern" examples within dual-use ethics discussions have all contributed towards the development of a "graduated scale of responsibility" with "tick box ethics" on one end, and voluntary moratoria on research on the other. These issues will be presented below, together with the dominant model of dual-use control currently being employed in discussions, which further influences how responsibilities are perceived for scientists.

## 2.2.1 Dual-Use Control and the "Web of Prevention"

From the discussions above, it is obvious that attempting to control the dual-use potential of research within the life sciences is no easy task. Such observations have been further emphasised by the awareness that previous models of control, such as those utilised by the nuclear science community, are unsuitable for application in this field. Thus, in most discussions on dual-use control recognising that it is unlikely that one single initiative will be able to address all the concerns – and that no "silver bullet" will address dual-use within the life sciences (NSABB 2006: 161) –is extremely pertinent.

Since the early 1990s there has been an emphasis on the idea of a "web" of measures to address the threat of biological weapons (Feakes 2007: 2) and involves multiple stakeholders in biosecurity. By the early 2000s this model of a "web" migrated to the dual-use discussion when the International Committee of the Red Cross (ICRC) launched an initiative on Biotechnology, Weapons and Humanity, calling for the reaffirmation of norms against biological weapons and better controls on potentially dangerous biotechnology (Kellenberger 2002, Feakes 2007). The ICRC termed this a "web of prevention", pointing to the crucial need for the involvement of health, security, governmental and societal communities in addressing the dual-use issue (ICRC 2003, Feakes 2007). This multifaceted method of control, echoed by the Lemon-Relman report, has become central to dialogues on controlling the dual-use potential of the life sciences.

Crucially, the "web of prevention" concept has built on existing biosafety and biosecurity initiatives to include security, law enforcement and life science organizations, and the coordination of international oversight. In one formulation it was suggested the web of prevention include initiatives such as:

- Export controls
- Disease detection and prevention
- Effective threat intelligence
- Biosafety and biosecurity initiatives
- International and national prohibitions
- Oversight of research
- Education and codes of conduct<sup>44</sup>

<sup>&</sup>lt;sup>44</sup>http://www.brad.ac.uk/bioethics/EducationalModuleResource/EnglishLanguageVersionofEMR/ See lecture 21. Accessed 14/03/2012.

This "web" schema has proved highly influential not only in distributing responsibility for dual-use control amongst multiple stakeholders, but also in showing how these stakeholders are interlinked in their creation of a "web of prevention". The "web" thus emphasizes distributed responsibility and harmonization between key stakeholder initiatives. In order for such goals to be achieved, this model thus requires a level of oversight to ensure the correct distribution of responsibility and responses.

In the last decade a number of countries have implemented dual-use controls that may be understood using the "web of prevention" model. Predictably, the application of the model to a specific setting has led to considerable variations in national "webs" (As discussed in Rappert 2007). Unsurprisingly, the most high profile involvement in the development of "webs of prevention" has come from Western countries such as the UK, USA and Australia (Rappert 2007). Thus, despite the differences in national applications, these webs have largely been underpinned by similarities in existing biorisk control strategies, resources available and bioethical background. These similarities have led to many discussions on harmonization between "webs" and the development of certain international schemes to strengthen this coordination.

This emphasis on the importance of harmonizing "web of prevention" initiatives is also endorsed by the regular observation that the impact of dual-use events will not be contained by geographical borders (NSABB 2006), but rather requires coordination of activities on regional, or indeed global levels. It is important to note, however, that most of the current discussions focusing on the harmonization of national "webs of prevention" focus on variations in *preferences* in web development, rather than the *ability* to develop such webs (Rappert, 2007). This may be seen as largely due to the limited number of countries that are involved in current debates – and the strong Western, developed background of these countries. In this manner (and in a similar fashion to research ethics), certain issues of contextual variations such as those involving incomplete biosafety and biosecurity regulations, have come to be

largely downplayed due to the similarities between the contextual environments of countries participating in these discussions.

This emphasis on harmonization in approaches to dual-use control has also been apparent in the development of codes of conduct for scientists, presented as lists of ethical principles which have been identified as important for addressing dual-use issues (Dando 2005). Although codes of conduct will be discussed more fully below, it is important to note that this tendency towards establishing a globally applicable dual-use bioethics through the identification of certain important ethical principles suggests a significant influence of research ethics on the developing field of dual-use ethics (based on the reasons identified in chapter one).

The distribution of responsibility within the "web of prevention" model between security, law enforcement and scientific communities has, to some degree, also resulted (intentionally or unintentionally) in the compartmentalization of duties towards dual-use control. Within the scientific community, responsibilities largely lie in biorisk management and responsible conduct of research, as well as fulfilling the obligations required of them by funding bodies, publishers<sup>45</sup>, national and institutional regulations and so forth. Thus, the "web of prevention" model has, at least in many developed countries, seen the development of specific responsibilities for scientists (in funding, publication and so forth) which are in line with the national approaches to dual-use control. In turn, this tendency towards role responsibility development, and similarly the RCR focus of these responsibilities, has significantly influenced ethical discussions of collective and individual responsibility for scientists. In the next subsections this will be discussed in further detail - particularly focusing on the influence that this approach has had on the development of responsibility rhetoric and the areas in which this approach could potentially experience problems.

<sup>&</sup>lt;sup>45</sup> Publishing requirements and funding obligations will be discussed in further detail later in this chapter.

#### 2.2.2 The Scientific Community's Responsibility for Dual-Use Control

Many references to the collective responsibility of scientists for dual-use issues have utilised the existence of a functioning "web of prevention" as a starting point for their analyses. In presenting a schema of distributed responsibility, the "web" model emphasises that scientists are not – and should not be – entirely responsible for controlling dual-use in their research. It is often emphasised that in addressing this problem they are supported by governmental, security, legal and healthcare stakeholders, all of whom hold some level of responsibility for ensuring widespread control.

On the other hand, however, as noted in the Lemon-Relman report: "scientists working in the life sciences arena are best suited to recognise the dual-use implications of these newly emerging technologies and fields of knowledge" (NSABB 2006: 193). Thus, as the "front line" of dual-use control, scientists are in a unique position for identifying and drawing attention to the possible misuse of their work. The participation of scientists in dual-use surveillance is of further importance due to the notion of autonomy – albeit assisted - advocated by the Fink report. The right to autonomy, however, comes with associated responsibilities for the life science community, as they assume responsibility for addressing and mitigating the dual-use potential of their research.

Although the notion of a collective responsibility by the scientific community for the dual-use potential of their research patently plays a central part in many discussions, it must be noted that it is rarely unpacked in detail. Indeed, the majority of texts resort to a generalised appeal to responsibility without closely examining the (ethical and philosophical) notions of a "collective" or "collective responsibility"<sup>46</sup>. Therefore, although there are many references to: "common culture of awareness and a shared sense of responsibility within the global community of life sciences" (NSABB 2006: 5), what this actually means is less clear. This situation is further complicated by the explicit mention of collective

<sup>&</sup>lt;sup>46</sup> As was elaborated on in some detail in chapter one.

responsibility in many of the codes of conduct being developed for dual-use. These generalised appeals to responsibility found in many of the reports and codes of conduct give little idea not only of how the "collective" is envisioned, but how such a collective may be created and perpetuated.

Seamus Miller conducted one of the rare philosophical studies on collective responsibility for dual-use issues. He builds on his previous theory of collective responsibility – that it is a joint responsibility of individual human persons (Miller 2001). He suggests that: *"the account of collective moral responsibility mirrors that of individual moral responsibility, the key difference being that the actions in question are joint actions, including joint epistemic actions"* (Miller, forthcoming: 11).

Miller suggests that in this structure each agent may have full or partial moral responsibility depending on their involvement in the action. Importantly, he also notes that there is a need to distinguish between cases in which agents have a collective moral responsibility for some joint action or its outcome from cases in which agents only have a collective moral responsibility for failing to take adequate preventative measures against sometime taking place. In the case of dual-use, he suggests, it is often the latter (Miller, forthcoming: 12).

In his article, Miller emphasises that the collective moral responsibilities of scientists are multiple, and that they can have differing responsibilities based on the object of their work. Thus, the collective moral responsibility of university scientists to acquire knowledge differs from those in commercial firms who are required to develop knowledge according to its commercial value. Significantly, he mentions that: *"these various collective institutional and moral responsibilities may be inconsistent with one another, notably the collective moral responsibilities scientists have as human beings and the institutional responsibilities that they might have as a member of a military research organisation"* (Miller, forthcoming: 12). Miller, however, does not examine how these responsibilities may be harmonised or standardised.

In his discussions on collective responsibility for dual-use issues, Miller draws heavily on his previous work with Michael Selgelid defining the distribution of responsibility for dual-use dilemmas (Miller 2007). The analysis arising from this research suggested that there were a number of options for decisionmaking in dual-use dilemmas, including actions by the individual scientist, an institutional, governmental, combination of institutional and governmental or independent authority (Miller 2007). In this study Miller and Selgelid recommend that the decisions for dual-use be taken either jointly by the institution and government, or by an international oversight body. Similarly, in his research on collective responsibility, Miller advocates the imposition of regulatory frameworks to govern behaviour amongst scientists. In a manner related to the "web of prevention" he suggests some of the specific regulatory measures that might be considered could include mandatory physical safety and security regulation, licensing of dual-use technologies and techniques, mandatory education and training, mandatory personnel security regulation, as well as censorship and constraint of dissemination (Miller, forthcoming: 12 -13).

Miller thus presents a multifaceted approach to issues relating to the collective within the scientific community that, at least in part, recognises the notion of global responsibility through the delineation of responsibility occurring through "joint epistemic actions". Using this notion, Miller proposes that scientists may be held at least partially responsible for any dual-use event based on their failure to take adequate preventative measures to stop the event from taking place. Nonetheless, if analysed closely it must be noted that Miller's approach to collective responsibility gives more than a passing nod to the current RCR stance on the subject (as discussed in 1.2.4).

By making the assumption that a functioning "web of prevention" and system of science regulation exists within any scientific community under examination, Miller largely excludes discussions on contextual variations that undoubtedly

exist between research environments. Although noting the possible variations relating to the object of research and role of the scientists in different professional contexts, Miller fails to explicitly deal with the possible variations within the research environments.

In failing to do so, Miller's proposal of partial responsibility based on failure to initiate preventative measures must surely be called into question. If scientists are unable to activate adequate dual-use response systems within their research (and national) environment, one must question the limits to which this notion of collective responsibility can be pursued. Similarly, although Miller has carefully elucidated a number of areas in which role responsibilities may be developed for scientists, it must be questioned what would happen to these discussions if the role responsibilities under discussion were out of sync with the environment in which they were to be applied.

These assumptions call into question the underlying assumption of collective responsibility as that is in relation to the aggregate phenomenon popular in RCR education, which Miller alludes to through his mention of: *"collective mirroring individual moral responsibility"*. Instead, as will be discussed in detail in chapter five, it must be questioned whether alternative models of collective responsibility may be more permissive towards including scientists on a global level. It is possible that the distributed responsibility that is advocated by the "web of prevention" should be accompanied, instead, by a model of collective responsibilities that more explicitly recognises the multifarious responsibilities to community, colleagues, and personal life that scientists negotiate on a daily basis, and the influence of their research environment on their perceptions of group membership and collective responsibility.

Nonetheless, within dual-use discussions, educational initiatives and codes of conduct, the notion of collective responsibility remains rather under-examined. Where it has been addressed, such as by Miller, it would appear that it is influenced by the RCR model towards not only promoting a variation of the

aggregate notion of collective responsibility (as discussed in 1.2.4), but also furthering the idea of "everyone pulling their weight" (as discussed in 1.2.1) though certain role responsibilities. As has been alluded to above, and will continue to be elaborated on in detail throughout this thesis, it is my proposal that such an approach to collective responsibility has the potential to cause considerable distress and confusion amongst scientific communities as they struggle to understand exactly how they fit into the *collective community of scientists* and what exactly this community is responsible for.

#### 2.2.3 Individual Responsibility for Scientists

The relative dearth of discussion on collective responsibility stands in contrast to the considerable attention that has been paid to individual responsibilities in dual-use discussions – particular those of scientists<sup>47</sup>. Despite such an endorsement, discussions on individual responsibilities have predictably proven extremely complicated due to the uncertain, future potential of dual-use events and the necessity of upholding to the best ability openness and freedom of research.

Interestingly, as will be discussed below, the bulk of these discussions depart from the broad sense of global responsibility advocated by Jaspers and Jonas<sup>48</sup>

, Dando, M. (2009) Bioethicists enter the dual-use debate. Bulletin of the

Atomic Scientists

<sup>&</sup>lt;sup>47</sup> Interestingly, few discussions regarding dual-use in the life sciences explicitly refer to the role responsibilities of the other partners in the "web of prevention".

<sup>&</sup>lt;sup>48</sup> Briefly, as discussed in chapter one, the ethics of responsibility, promoted by Hans Jonas offers a modification of Kant's categorical imperative and proposes an obligation to: *"[a]ct so that the effects of your action are compatible with the permanence of genuine human life"* Jonas, H. (1979). <u>The Imperative of Responsibility: in Search of Ethics for the Technological Age</u>. Chicago, University of Chicago Press.

<sup>.</sup> This imperative demands foresight and precaution from each scientist and the scientific community. Jonas argues that a prospective responsibility to care and avoid harm is particularly important in modern science, as it is inevitably linked to technology and thus impacts the real world in ways for which scientists are accountable Ehni, H. J. (2008). "Dual use and the ethical responsibility of scientists." <u>Arch. Immunol. Ther. Exp</u> **56**: 147 - 152.

and "global citizenship" to instead focus on understanding *how* and *for what* scientists are responsible with regards to their work. Thus, in a similar fashion to the research ethics approach (as delineated in 1.2.4), it would appear that many discussions of individual responsibility for dual-use issues are concerned with identifying role responsibilities for scientists. This approach, as will be critically elaborated on at the end of this section, has been highly influential in the development of dual-use education.

Most discussions on individual responsibility in dual-use agree that assigning individual scientists sole responsibility for controlling the dual-use potential of their work, and for averting dual-use events is unfeasible (Miller 2007, Kuhlau 2008). Indeed, as suggested by Kuhlau and her colleagues, although "(*t*)he misapplication of peacefully intended research may cause moral distress among scientists, … it is difficult to argue that researchers should (solely) be held morally accountable for harm caused by unforeseen acts of misuse" (Kuhlau 2008: 483). Nonetheless, despite absolving scientists from full responsibility, an overwhelming majority of studies agree that scientists bear some responsibility for dual-use.

A survey of the existing literature presents a mixed bag of answers to the question: *what are scientists responsible for in dual-use*? As any dual-use event is, by its very nature, uncertain and in the future, how far the individual responsibility of the scientist can be extended is open to considerable discussion. Many of the attempts to grapple with this issue have utilised the Precautionary Principle and the Doctrine of Double Effect to highlight a generalised moral duty to minimise the harm arising from any research misuse without committing scientists too strongly to sole responsibility.

Thus, while there is a general recognition amongst the dual-use community that some form of responsibility is attributable to the individual scientist, the question of responsibilities for dual-use have evolved to become: *"not how far a scientist is responsible for the intended effects of his action, but how far he is*  responsible for the foreseen effects of his research, for their prevention, and also for the effort to predict certain effects. The answer will depend on how the prospective responsibility related to the duties corresponding to the role of the scientist and the scientific community will be defined in the given case" (Ehni 2008: 148).

Ehni's quote highlights two important issues. Firstly, that unlike most other discussions on responsibility which deal with foreseeable or preventable activities, the absence of these prerequisites in dual-use has made defining responsibilities extremely complicated. Secondly, attempts to sidestep these complications have led to an emphasis on establishing the *duties* of scientists that will define adequate dual-use responsibilities. Thus, many discussions have focused on developing role responsibilities that will adequately interpret scientists' individual responsibilities for the dual-use potential of their work. This has been approached in a more theoretical stance by dual-use bioethics and in codes of conduct, and in more pragmatic ways by the development of regulations and legislations.

In 2008 two separate papers were published on the ethics of responsibility for dual-use issues. In each of these papers the authors attempted to identify specific duties that would demarcate the limits of individual responsibility within the scientific community. The first paper was published by Hans-Jörg Ehni<sup>49</sup> who, although considering responsibility as framed by Hans Jonas and Niklas Luhmann, proposed a specific set of duties for scientists which lie in between the two positions and included:

- not to carry out a certain type of research
- systematically to anticipate dual-use applications in order to warn of dangers generated by them
- to inform public authorities about such dangers
- not to disseminate results publicly, but keep dangerous scientific knowledge secret (Ehni 2008: 150).

<sup>&</sup>lt;sup>49</sup> Institute of Ethics and History of Medicine at the University of Tübingen in Germany.

Ehni recognised that these duties rested on the recognition that retrospective responsibility for dual-use events, and could at best be considered "imperfect duties" according to the Kantian designation. Nonetheless, he proposed that these duties represented the middle ground between the *lassaiz faire* attitude of moral scepticism and the need to restrict research and publication which, he suggested, might follow from Jonas' position. In his view, *"only a mixed authority which is constituted by the scientific community together with governmental bodies, but with the participation of scientists meeting their responsibilities so far as possible, can solve the problem"* (Ehni 2008: 151), yet it remains a necessity for the individual scientist to be aware of the potential for dual-use and to contribute his or her expertise to dealing with it.

The other paper was published by Frida Kuhlau and her colleagues<sup>50</sup>. They began by recognising the limitations of abstract formulations of responsibility, stating that: *"[a]lthough bioterrorism might be perceived as an imminent threat … it is beyond the responsibility of most 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*" (Kuhlau 2008: 477).

Similarly to Ehni, Kuhlau and her colleagues emphasised how difficult it would be for scientists to consider all the possible negative implications of their work, noting that *"many obstacles remain with respect to clarifying what is foreseeable and how to foresee potential misuses"* (Kuhlau 2008, Dando 2009). They note that what constitutes as "harm" is not always apparent in ethical discussions, and highlight the need to clarify the differences between intentional and unintentional actions, harm and the risk of harm, and awareness of harm (Kuhlau 2008). Using this awareness of the distinctions within the concept of harm, they proposed five obligations by which it would be reasonable to expect scientists to prevent harm. These included:

<sup>&</sup>lt;sup>50</sup> Centre for Research Ethics and Bioethics at Uppsala University in Sweden.

- it must be within their professional responsibility.
- it must be within their professional capacity and ability.
- it must be reasonably foreseeable.
- it must be proportionally greater than the benefits.
- it must be not more easily achieved by other means (Kuhlau 2008: 481 482).

With this bounded definition of harm, Kuhlau et al then went on to propose a number of different duties for life scientists in relation to dual-use. These were:

- The duty to prevent bioterrorism.
- The duty to engage in response activities.
- The duty to consider the negative implications of their work.
- The duty not to publish or share sensitive information.
- The duty to oversee or limit the access to dangerous materials.
- The duty to report activities of concern (Kuhlau 2008: 483 486).

Both the duties proposed by Ehni and those of Kuhlau et al represent examples of ethics that reflect specific political requirements and priorities in their development role responsibilities. Ehni and Kuhlau both agree that the primary obligation of the individual scientists lies in identifying the potential harm within their research and informing other of it. This stance echoes that which has been promoted more generally by the NSABB<sup>51</sup> and others. In keeping with the

<sup>&</sup>lt;sup>51</sup> The Lemon-Relman report states that: *"[s]cientists working in the life sciences arena are best suited to recognize the dual-use implications of [their work], but they must develop a broadly distributed culture of awareness and responsibility if they are to recognize and shed light on potentially dangerous activities as they occur"* NSABB (2006). Globalization, Biosecurity and the Future of the Life Sciences. Washington D. C., The National Academies Press.

Western emphasis on bioterrorism and the need to manage the potential for nefarious misuse, both Ehni and Kuhlau et al structure their duties so as to specifically confront these issues. This allows them to clearly delineate some boundaries in an otherwise nebulous field.

However, what becomes clearly apparent when these duties are considered is that they have been constructed to fit within a coherent "web of prevention" which offers the scientists the tools needed to address these responsibilities. Thus, these current formulations of individual responsibility within dual-use discussion can be taken to reflect and suit the needs of a specific research community within a specific research environment and "web of prevention".

What is less apparent, however, is whether these duties can be transferred between communities of scientists without prior reference to the variations between research contexts. Nonetheless, the current low level of discussions on responsibility in dual-use, and the close association of dual-use ethics with research ethics makes it highly likely that this may indeed be occurring. Furthermore, in a similar fashion to research ethics literature, it is possible that this could create significant problems would be overlooked largely because of a lack of variation between the contexts that studies such as those above are considering – indeed, contextual variations between research environments in Scandinavia or the EU may be minimal.

However, as emphasised in chapter one, while the de-emphasis of contextual variations and the promotion of a global ethical approach may be possible in research ethics, it is less likely to be successful for broad social issues such as dual-use. Thus, the transposition of role responsibilities such as those described above to research communities with considerably different cultural, physical and regulatory environments may be extremely problematic, based on a number of interrelated issues.

Firstly, that any subscription towards responsibility for dual-use depends heavily on the individual scientist's interpretation and endorsement of what comes to count as "risk" and "benefit" arising from scientific research which arises from their socio-cultural environment. Secondly, attempts to translate this broad social responsibility into practical duties are undercut by variations in the embodiment of the "web of prevention" within a specific context. As these duties hinge not only on a functioning system of control within research, but also on the adequate distribution of responsibilities amongst stakeholders, the importance of recognising the context of science cannot be overemphasised. Thirdly, in the absence a functioning "web of prevention", as may feasibly be the case in many developing countries, it must be questioned whether these duties are sufficient towards addressing individual responsibilities amongst these As many of these duties are associated with specific role scientists. responsibilities within laboratories (such as upholding biosafety and biosecurity protocols) transposing Western role responsibilities may cause considerable problems or scientists.

Nonetheless, within dual-use ethics discussions, such issues are rarely – if ever – alluded to. The small number of ethical analyses of individual responsibility, together with the close relation that dual-use has to biosafety and biosecurity, I suggest, has often led to the promotion of Western role responsibilities as *globally applicable* role responsibilities. Thus, many current initiatives that address individual responsibilities, in a similar fashion to biorisk management, have attempted to clearly define the role responsibilities associated with dual-use. This has resulted in a number of different "intervention points" including pre-publication review, funding application review, and research ethics review. Thus, in a similar manner to biorisk management, dual-use management has become characterised by role responsibilities that relating to "check points" at salient points during research progression, and which are promoted around the world as acceptable duties for scientists.

The subtle differentiation between *what* scientists are responsible for, and *how* they should act responsibly has also been less well recognised in discussions

on individual responsibility. The specific attributes that have become associated with the concept of dual-use have resulted in solution-driven ethics, rather than breeding a dynamic and continual process of negotiation which would be extremely pertinent in non-Western environments.

Much of the discussion on individual responsibility in dual-use has centred on the establishment of role responsibilities for scientists that is unsurprising given the placement of dual-use at the end of the biorisk spectrum. This placement has seen a strong association of dual-use with the practical, solution driven approach that characterises research ethics. This has had further implications for ethics pedagogy and dual-use awareness raising amongst the science community, as many initiatives strongly resemble elements of the RCR model discussed in 1.2.4. Bearing in mind the hesitations listed above, however, one must question how far such an approach will be successful in truly allowing scientists to access the concept of global responsibility.

## 2.2.4 Dual-Use Ethics and RCR: Practical or Limiting?

By examining the historical events leading to dual-use concerns within the life sciences and the influential reports which have shaped contemporary discussions on the issue, a number of characteristics of current stance of dualuse ethics evidently require further examination. Firstly, no doubt in part due to the events of 2001 and the subsequent climate of security-awareness, current dual-use rhetoric – dominated as it is by influences from the USA and UK - is extremely closely aligned with the fields of biosafety and biosecurity. Secondly, the development of a "web of prevention" model for addressing dual-use issues has focused considerable attention on defining role responsibilities and re-examining existing measures of responsibility distribution and control.

Furthermore, although no doubt in part due to the relatively small number of studies dealing directly with dual-use ethics, the brief examination of trends in

the field above pay little attention to contextual variations that will exist between communities of scientists. Instead of examining the effect on dual-use discussions – and hence dual-use ethics - of the cultural, physical and regulatory differences that exist between communities of scientists, current ethics discussions often remain curiously mute on the topic. Instead – either as an error through omission, or as a recognised goal – it would appear that current tends tend to promote the development of a "globally applicable" ethical approach to dual-use ethics. It is highly likely that this is due to two important issues: firstly, that due to the historical legacy of dual-use as a biosafety concern, and the dominating influence of the USA on dual-use discussions, dual-use bioethics is largely underpinned by research ethics and informed by the RCR model, as discussed above.

It would therefore appear that the (explicit or implicit) association of dual-use ethics with RCR and research ethics has left an indelible impression on this emerging area of study. This, I propose, has led dual-use ethics to possess a number of characteristics that were discussed in section 1.4 – particularly the promotion of role responsibilities in the field of individual responsibility, the promotion of a variation of an aggregate form of collective responsibility, and the promotion of a global ethical system to guide scientists around the globe (which I reject as spurious).

Furthermore, it seems likely that the legacy directly related to FFP misconduct of a "minimum standard of responsibility" has some traction in dual-use ethics discussion. This notion necessarily focuses predominantly on what should *not* be done, rather than what *should*, and the contrast between preventing scientific misconduct and fostering good conduct as an issue in RCR training was discussed in chapter one. Similarly in dual-use bioethics, it appears that there has been a predominant focus on defining the limits of duties to *stop* dualuse events from happening, rather than fostering global responsibility and sense of community involvement. However, unlike FFP, it is unlikely that in dual-use discussions "good conduct" can be easily equated to the absence of misconduct. All these issues have had a significant impact not only on the development of dual-use ethics, but only on the design and execution of dual-use awarenessraising initiatives. As the ultimate aim of dual-use education is to create a global awareness for these issues, one must question whether the approach delineated above is the best means of fostering a global sense of responsibility. This will be discussed in more detail below.

## 2.3 Raising Dual-Use Awareness Amongst Scientists

Recent years has seen a rise in the prioritisation of dual-use education for scientists. Indeed, the recent BTWC intersessional meetings have emphasised the need to improve dual-use awareness amongst the science community (NRC 2011). This has been widely endorsed by national stakeholders such as the NSABB who explicitly mentioned the need for the: *"establishment of a decentralised, globally distributed network of informed, concerned scientists who have the capacity to recognise when knowledge or technology is being used inappropriately or with the intent to cause harm"* (NSABB 2006: 193). In addition to the importance of scientists as the "first line of defence" in dual-use surveillance, ethics education has also been recognised as a vital component of many of the other dual-use control initiatives that involve scientists. These, as mentioned above, include pre-publication review of journal articles, self-examination and review of funding application and the ethical review of research.

Similarly, capacity building initiatives within the scientific community are also recognised as a vital element for the development of the model of assisted autonomy as advocated by the Fink and Lemon-Relman reports (AAAS 2010) in which scientific populations have a high level of involvement in the governance and regulation of dual-use controls. Thus, improving education, and developing codes of conduct and systems of informal mentoring have all

been identified as vital components for developing the *"common culture of awareness and a shared sense of responsibility"* which was advocated by the Lemon-Relman report (NSABB 2006: 5).

Nonetheless, despite this considerable endorsement, teaching dual-use ethics and developing systems for raising awareness within scientific communities are by no means easy tasks (NRC 2011). This section briefly reviews current methods of raising dual-use awareness, and how the characteristics of dual-use ethics are incorporated into these initiatives. In this manner, the section carefully considers how these methods of capacity building are similar to those employed in RCR education. The section concludes by questioning whether this twin approach of RCR-influenced ethics and education may diminish the effectiveness of these undertakings. In particular, such hesitations may prove particularly pertinent in traditionally non-Western countries where differences in research cultures, social priorities and research facilities may all contribute significant problems.

## 2.3.1 Formalised Dual-Use Education of Life Scientists

Ethics education for life scientists has been discussed in reviews of the BTWC since 1991, and has featured prominently in most dual-use reports. It has been recognised that, in addition to reinforcing the norm against biological weapons, education plays a valuable role in ensuring the model of autonomous self-governance advocated by the science community (Rappert 2007: 51), vis-à-vis the ability of the scientific community to: *"take pre-emptive steps to protect the integrity of science and to minimize the risk of misuse of dual-use research of concern"* (AAAS 2009). However, despite the enthusiasm with which dual-use education has been promoted and endorsed, it has yet to make a considerable impact within science education (Rappert 2010, Sture 2010).
As yet, most educational initiatives depend on institutional interest, and the availability of biosecurity topics within university education has been the subject of a series of international surveys in the USA (NRC 2009), Europe (Mancini 2008), the Asia-Pacific region (Minehata 2010), Japan (Minehata 2010), Israel (Minehata 2009), and the UK (Revill 2009). The data from these surveys all suggest that globally the current exposure of undergraduates to biosecurity issues is limited. Data on postgraduate or professional development courses are even scarcer, but it seems unlikely that these will differ from the undergraduate situation.

Nonetheless, as discussed further below, it must be assumed that (regardless of the presence of formal training modules), that a significant amount of training and information about responsible conduct and biosafety are provided informally through laboratory mentoring by senior researchers (NRC 2011: 4). Therefore the current penetrance of dual-use awareness may not be reflected solely through syllabi. Regardless of such observations, however, surveys (AAAS 2009), fieldwork (Rappert 2007) and anecdotal evidence (NRC 2011) all tend to suggest that awareness of the concept of dual-use and its associated issues is very low within the scientific community. Thus, when considering dual-use education it is often important to bear in mind that it is a subject that most learners have no prior experience of.

The need to significantly increase capacity in dual-use education, the challenges of teaching a topic such as dual-use, and the likelihood that learners will have no prior experience in the field have all become significant considerations in discussions in dual-use education. While the field has been underpinned by the belief that "no one size fits all" (NRC 2011: 5), and many educators recognise the need to design courses that are presented in a contextually-sensitive manner, many of the current courses available have degrees of commonality in their content – both historical and ethical (NRC 2011). The historical content often includes material on the BTWC and national regulations; the history of biological warfare and the role of scientists in past programmes; as well as the dual-use dilemma (Mancini 2008).

The majority of current dual-use educational initiatives occur as part of a broader education on the research ethics (predominantly following the RCR model), in basic sciences courses, as part of biosafety training, or within bioethics (NRC 2011: 4), and stand-alone courses are rare. Indeed, current thought advocates the incorporation of dual-use issues into channels through which life scientists already receive their exposure to the issues of responsible conduct (NRC 2011: 6). The AAAS survey of attitudes to dual-use in the American life science population suggested that there may be considerable support for models of oversight that rely on the responsible conduct of research and self-governance by the scientific community (AAAS, 2009: 2).

Within these courses, the ethical content is often a mixed bag of different issues, and may contain some of the following: references to applied ethics and bioethics; synopses of the Fink and Lemon-Relman reports and their recommendations; an overview of the ethical obligations of the BTWC; and some discussion on risk/benefit analyses, the precautionary principle and the doctrine of double effect (NRC 2011). In a similar fashion to other areas of ethics education, teaching dual-use ethics is complicated by the close link between *what* ethics is being taught, and the questions of *how* it is taught, and *to what end*? Considerable discussion exists regarding the possibility of an authoritative voice in educational initiatives, and whether scientists should be educated by scientists or philosophers. As with all ethics education, it must be questioned whether the aim of the undertaking is to sensitise scientists to the ethics associated with their research, or to develop "ethical" scientists (Rappert, 2007b).

Many dual-use ethics courses also present some of the role responsibilities (particularly the individual ones) discussed above. In many cases, and no doubt due to the presentation of dual-use as an extension of biorisk topics, this approach may reinforce the idea of dual-use awareness being simply the fulfilment of a set of specific role responsibilities that integrate with a broader

web of distributed responsibilities. Furthermore, dual-use ethics course designs often lack discussions on what a social contract between science and society means in that particular educational context, what priorities are being promoted in this contract, and whether a notion of a "global scientific ethics" adequately reflects dual-use concerns. All of these issues, as suggested in chapter one, could be taken as a result of the close relationship between dual-use and biorisk education. While, of course, it is possible that such topics are discussed informally between the teacher and the pupils, this can by no means be assumed.

In addition to conventional educational initiatives, the recognition of the patchy and unstandardized nature of ethics education for scientists has also led to the development of a number of online ethics courses for life scientists<sup>52</sup>. The content and style of these courses varies considerably, it must be noted and only a few of these resources are explicitly designed to support active and engaged learning (NRC 2011: 4). Recently there have been some attempts to design online repositories that provide "template modules" as teaching resources for educators interested in designing ethics education for life scientists. Most of these courses broadly address research ethics (such as UNESCO 2008), however there are an emerging few, such as that produced by the Department of Peace Studies at the University of Bradford, which specifically focus on dual-use<sup>53</sup>. It is important to note that, perhaps in part due to their focus and in part due to their ethical background, these courses all promote the notion of a "global scientific ethics". As will be discussed in detail in chapter four, while these courses present a potentially valuable tool for dualuse aware educators, the lack of sufficiently trained educators "on the ground" and the lack of contextuality in the content of these courses makes any projections of the limits of their utility difficult.

<sup>&</sup>lt;sup>52</sup> Online educational modules include those developed by the Department of Peace Studies at the University of Bradford, the Center for Arms Control and Non-Proliferation, Federation of American Scientists and the Southeast Regional Center of Excellence for Emerging Infections. <sup>53</sup> The University of Bradford has also started developing "Train the Trainer" programmes to

<sup>&</sup>lt;sup>53</sup> The University of Bradford has also started developing "Train the Trainer" programmes to increase the number of dual-use educators. These initiatives, however will not be discussed in this thesis mainly because the content which is taught to the trainers is largely similar to that offered in the general dual-use education.

Dual-use education as it stands is thus a complicated field. Not only does it have to contend with the general problems associated with ethics education<sup>54</sup>, but the attempts to gainfully involve scientists in dual-use discussions can be said to be hampered by a number of different considerations, which become even more pertinent when one considers educating scientists outside of developed countries. These can be summarised accordingly:

- Are the differences in the concept of responsibility inherent in the role responsibilities of RCR and global responsibility of dual-use bioethics sufficiently distinct within one single course covering a spectrum of risk, or does the broad global responsibility approach for dual-use responsibility become meaningless?
- Does the strong focus on role responsibility within RCR education that is often adopted in dual-use education reduce responsibility to a bureaucratic exercise – and one which loses large amounts of meaning due to the lack of immediacy of the threat being controlled for?
- Does the promotion of the notion of a "global scientific ethics" and a relatively low level of discussion about contextuality present in RCR education influence how principles are addressed in dual-use education?

Current educational initiatives for dual-use therefore may be said to have a close connection to research ethics. Not only is the topic of dual-use (if addressed at all) usually added on to existing research ethics education, but within dual-use education itself the influence of the RCR model is clearly apparent. Dual-use ethics is often presented as relating to a "global bioethics" in which scientists have specific role responsibilities. This approach has also been echoed in the other dual-use ethics developments, most particularly in the emerging codes of conduct.

<sup>&</sup>lt;sup>54</sup> These were discussed by Rappert in (2007b), and can be summarized as the following questions: is it expected that initiatives will lead individuals to act differently, must researchers rethink the basic way in which they conceive their work, how likely is the potential for disagreement about the issues at stake and what needs to be built into the process of education, how are the aims of eliciting comprehension and providing knowledge balanced, is education valuable in itself, or is it part of a process designed to aid some outcome?

#### 2.3.2 Codes of Conduct

In the last two decades, the idea of developing codes of conduct for scientists has been gaining considerable traction. Increasingly, a variety of professional organisations, research institutions and scientific societies in the life sciences have developed and adopted ethical codes for their members. The majority of these codes of conduct have focused on research ethics and have attempted to delineate the ethical requirements of professionalism within a specific field.

Within dual-use discussions, codes of conduct have also been enthusiastically endorsed. The BTWC<sup>55</sup>, as well as many reports and research articles (Such as NRC 2004, NRC 2004, NSABB 2006) have advocated the development of codes of conduct<sup>56</sup> as a means to develop responsibility amongst the science population. Furthermore, several international forums have made efforts to construct globally applicable sets of principles guiding the development of specific codes of conduct relating to potential dual-use research in the life sciences (NSABB 2006: 189). These bodies include the BTWC, UNESCO, and the ICRC, while the InterAcademies panel has developed resources for the development of future codes (IAP 2005).

It must be noted that, in a similar manner to educational initiatives, the issue of dual-use is not usually the sole subject of these codes. Instead dual-use tends to be one element of the broader codification of the ethos of scientific research (Jones 2007). Prototype codes articulate the goal for life sciences research and

<sup>&</sup>lt;sup>55</sup> In November 2002, at the conclusion of the intersessional meeting of the Fifth Review Conference, State Parties to the BTWC agreed that the topic for the 2005 intersessional meetings would be the "content, promulgation, and adoption of codes of conduct for scientists".

<sup>&</sup>lt;sup>56</sup> It must be noted that codes of conduct can be differentiated into three different types: codes of ethics (aspirational), codes of conduct (educational/advisory guidelines for action), codes of practice (enforceable prescriptions of certain behaviour)<sup>56</sup>. Codes are currently being investigated in many areas and can be further divided into universal codes, scientific society codes and institutional or workplace codes. While workplace codes are quite common, since 2001 there has been a renewed interest in establishing universal and scientific society codes. Understanding the purpose and expected outcomes of any code is a vital component of its utility, and frequent misunderstandings regarding the limits of use and application of codes is a major hurdle to their effectiveness.

the responsibilities associated with the freedom of exploration, the principles for the practice of science, and the virtues of the scientists themselves (Jones 2007). These ethical norms are most often articulated as normative principles, however, and are not prescriptive in the manner in which these principles should be articulated into daily practice. Thus, I suggest, codes of conduct may often mistaken be mistaken for synopses of "global ethical systems" instead of an identification of norms that require contextualisation within a specific environment.

Despite the assumption that ethical codes contribute towards fostering ethical conduct, little is known about the effectiveness of these codes in practice (NSABB 2006: 190). Issues relating to awareness, integration and compliance are well recognised in many fields (Luegenbiehl 1991, Doig 1998, Higgs-Kleyn 1998). Nor is it likely that codes of conduct will deter individuals committed to malicious misuse of scientific research. Nonetheless, codes of conduct remain an integral focal point in developing awareness regarding dual-use issues. In a similar fashion to the Hippocratic Oath and the Declaration of Geneva, it is hoped that the application of ethics to science from its inception will allow scientific research to conform to the ethical norms and requirements of society<sup>57</sup>.

With regards to dual-use issues, advisory codes tend to be the most common and aim to increase knowledge and awareness on a number of key ethical issues. Current codes of conduct identify core traits related to individuals such as honesty, truth, respect, openness, accuracy, collaboration, fairness, conscientiousness, and loyalty. In addition, they usually promote a number of core traits related to the community which include social responsibility, sustainable development, social welfare, gender equality, peace, human rights,

<sup>&</sup>lt;sup>57</sup> As discussed further in Altas, R. M., Somerville, M. (2007). Life sciences or death sciences: tipping the balance towards life with ethics, codes and laws. <u>A Web of Prevention</u>. B. Rappert, McLeish, C. London, Earthscan.

environmental responsibility, socio-economic development and equity, scientific freedom and democratic development (UNESCO, Resnik 2010).<sup>58</sup>

Developing a code, it has been noted, is not merely a matter of identifying which values are intrinsic in science. It also needs to be a matter of negotiation aimed at creating a new perspective of trust in relation to society. Interestingly, this stance has been reiterated by the InterAcademy Panel (IAP) and the NSABB, which have both recognised the limitations of a universal code and suggested that it is unlikely that a single code will be uniformly acceptable especially if it contains the relatively specific features of a code of conduct (IAP 2005, NSABB 2006). Furthermore, the translation of the code of conduct into part of a lived culture of a social group remains a considerable problem (NSABB 2006: 191). However, as I mentioned above, discussions regarding these issues are not prominent in dual-use ethics. How the basic values of science are connected with the notion of social responsibility and accountability remains a difficult topic. Therefore, it may be said that although codes of conduct, and the accompanying ethics education have been had a large amount of support at a general level, little in the way of consensus is present on the level of specifics (Rappert 2007).

Furthermore, in light of the discussions offered in chapter one regarding the differences between interpretations of responsibility in research ethics and in discussions of broad social issues, it would appear to me that codes of conduct are additionally connected to another area of problems. If, as with dual-use, ethical codes are developed which address both research ethics topics and broad social issues, one must consider whether confusion may arise within scientific populations regarding the different manners in which ethical principles can be interpreted within these distinct topical areas. For example, can the notion of "responsibility" in research ethics be taken as equal and equivalent to "responsibility" as it is used in dual-use discussions?

<sup>&</sup>lt;sup>58</sup> These ethical principles will be further examined in the following chapter.

Despite these hesitations associated with codes of conduct, it must be noted that the codification of principles remains potentially useful tools for educating scientists and raising awareness of ethical obligations including principles such as beneficence, non-maleficence, respect for life, maintaining trust and acknowledging individual and collective responsibilities (Somerville 2005). It is possible that the development of a robust set of ethical norms may assist members of a discipline coordinate activities and promote the aims and goals of the research (Resnik 2010). However, how to ensure that codes of conduct are not misinterpreted as synopses of a "global ethical system" which transcends national borders, disciplines and subject matter remains complicated. Indeed, how codes of conduct may be made pertinent within a specific research context is largely unexamined, and assumed to be facilitated by informal teaching by research staff.

#### 2.3.3 <u>Teaching by Example: Raising Dual-Use Awareness</u>

Throughout this chapter reference has been made to the concept of "self governance" within the science community for dual-use control. The belief, advocated in different forms by the NSABB and most other governmental agencies, being that as far as possible scientists should be in control of assessing their research for dual-use complications and raising awareness when necessary.

In an interesting survey conducted by the AAAS, it was revealed that although awareness of the dual-use concept was low amongst surveyed scientists (based in US institutes funded by NIH grants), many of them reported regulating their research informally for what could be perceived as dual-use concerns. The report stated that: *"[f]ifteen percent of the respondents (260 individuals out of 1744) indicated that they are so concerned about dual-use research that they have taken actions, even in the absence of guidelines or mandatory regulations from the US government. Some respondents reported that they had broken collaborations, not conducted some research projects, or not communicated*  research results. The results indicate that more scientists have modified their research activities than some members of the committee expected on the basis of previous reports of manuscripts that have been modified or not published because of dual-use concerns" (AAAS 2009: 5). This, the survey suggested, indicated that dual-use self-governance for the responsible conduct of research might be a suitable model of protection (AAAS, 2009: 5).

Such observations have been highly influential in conceptualising a system of information dissemination and awareness raising, and has led to the devolution of considerable responsibility for dual-use to the PIs. Indeed, as previously mentioned, the NSABB-proposed divide between "dual-use research" and "dual-use research of concern" has (NSABB 2007)<sup>59</sup> led to the proposal of a "check list" of considerations to be applied by the PI to the former research. The NSABB proposed that the initial review of whether or not the research was "of concern" should be carried out by the senior project leader, who should ask of their work: "... based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or material" (NSABB, 2007: 17). The model of self-governance hinges on the traditional model of pedagogy within the life sciences – that of a chain of mentorship and a high degree of informal education within research settings to ensure that the PI transmits concerns to the rest of the research team.

The model of teaching by example as relates to dual-use depends on three main components. Firstly, that the PI has had sufficient training in dual-use to be able to understand the concept and implement awareness in daily research

<sup>&</sup>lt;sup>59</sup> This approach was based on the low identification rate of research "of concern" within journals. The NSABB proposed that the initial review of whether or not the research was "of concern" should be carried out by the senior project leader, who should ask of their work: "... based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or material" (NSABB, 2007: 17). Alternative systems have been proposed, such as the "Biological Research Security System" offered by the Center for international and Security Studies at Maryland, but the NSABB approach has been by far the most influential.

practices. Secondly, that the funding, publishing and other regulatory requirements that depend on the actions of the PI are designed to stimulate critical reflection, and are not dismissed as bureaucratic exercises. Thirdly, and perhaps most importantly, that the PI see value in the concept of dual-use, the proposal of harm arising from research, and the importance of its regulation. If the PI does not value the concept of dual-use it seems highly unlikely that a culture of dual-use awareness will be fostered within their research group.

The reliance of teaching by example is definitely influenced by the association of the dual-use concept with biosafety and biosecurity issues. These areas also rely heavily on teaching by example and the social transmission of safety and security principles to students within the laboratory, and place a high premium of continual surveillance and monitoring by the PI. However, unlike dual-use, biorisk discussions have an obvious advantage, as they are associated with definite right and wrong outcomes, and prescribed models of behaviour. Thus, teaching by example is a practical exercise, and not one (as with dual-use) that requires a great deal of ethical reflection and personal conviction.

Discussions of teaching by example in dual-use tend to the issues mentioned above, or the differences between the outcomes of biorisk teaching by example and that of dual-use. It is possible that these caveats may result in an unreasonable amount of strain being placed on PIs. Indeed, without critical analyses on how to foster a culture of ethical research and dual-use awareness within laboratories, it seems unfair to place the bulk of the dual-use burden at the door of the PI.

To date there is little information on the effectiveness of teaching dual-use issues by example. Furthermore, there is even less information on how best these requirements should be met by the PIs themselves. Within dual-use discussions the concept of an "ethical research culture" has not been properly addressed, and little has been said on how exactly dual-use awareness is fostered within laboratories.

# 2.4 Reassessing the Situation

This chapter has examined how the evolution of dual-use concerns within the life sciences has been heavily influenced by Western security concerns and practical research ethics. In a similar fashion to the hesitations discussed in chapter one, this chapter suggests that it may be useful to carefully re-examine the limits of this close relationship, particularly in light of developing pedagogical initiatives to raise awareness. This will not only potentially benefit scientists working in traditionally Western countries, but also those working in non-Western environments such as occur in many developing countries.

As discussed at length in this chapter, a large number of current dual-use discussions may be characterised by their strong security focus on bioterrorism, as well as the close association between dual-use and biorisk management and research ethics. In chapter one a number of issues were identified which, I proposed, had the potential to detract from the educational success of using RCR-related pedagogical styles to address broad social issues. Similarly, it would appear to me that the current approach to dual-use education might experience similar issues. These are briefly enumerated below, and will subsequently form the basis of the empirical investigations that are discussed in chapters three to six.

#### 2.4.1 <u>Tightly Bounded Content for Ethical Principles</u>

Chapter four examines the issues relating to the "content of ethical principles" as introduced in section 1.4.1. It is my belief that the (intentional or unintentional) promotion of the idea of a "global dual-use ethics" and the absence of critical engagement in the content of the ethical principles underpinning dual-use (as a legacy from research ethics and particularly RCR) has the potential to cause considerable confusion amongst communities of scientists. In particular, I suggest that the contextual interpretations of key

ethical principles such as "harm" and "beneficence" may result in considerably different interpretations of the concept of dual-use and its brevity. Indeed, it appears likely that a lack of critical discussion on this issue may have severe repercussions on the development of an international dialogue on dual-use issues – particularly relating to the involvement of previously marginalised scientists in current debates.

Such considerations are of significance to educational initiatives and the development of codes of conduct. Particularly relating to online educational courses and codes of conduct, it must be questioned whether a lack of dialogue regarding the contextually informed manner in which principles may be interpreted *in situ* could either detract from their usefulness or create ethical confusion. In most current educational discussions the majority of the discussions on contextuality focus on *how* educational initiatives differ across cultures, yet it must be questioned whether the *content* differs as well – despite appearing similar on the surface.

In chapter four these considerations are examined empirically by comparing the manner in which scientists in African or UK laboratories discussed the concept of dual-use. In particular, as will be carefully elucidated throughout the chapter, scientists were encouraged to discuss the concept of dual-use in relation to their perceptions of the possible harms and benefits arising from their research. In so doing it was possible to get a better understanding of the content that they attributed to these principles, and how they differed between sites.

# 2.4.2 Overemphasis on Role Responsibilities

Within the RCR model, as discussed in chapter one, the notion of role responsibilities play an important role in expected behaviour delineation and governance. Furthermore, in many cases awareness and avoidance of misconduct through fulfilling role responsibilities is broadly equitable to good

conduct, which places the duty to fulfil role responsibilities in an extremely important position. In this chapter it was noted that role responsibilities and the avoidance of misconduct also play an important role in most dual-use discussions, as attempts are made to identify specific duties for scientists within a broader web of dual-use prevention.

However, as discussed in chapter one, this raises two different problems. Firstly, it is my opinion that in many cases attempting to reduce responsibilities for broad social issues to specific duties may detract from the vital need to build a notion of global responsibility. Secondly, as role responsibilities, by definition, reflect the responsibilities attributed to a particular profession *within a particular society*, the transportation of role responsibilities beyond the community in which they are developed is potentially problematic. While, as mentioned in chapter one, these problems are less apparent in research ethics, they undoubtedly come to the fore in broad social issues such as dual-use.

Chapter five empirically examines this idea, focusing on whether the emerging role responsibilities associated with dual-use controls facilitate or deter scientists from engaging with the global responsibility of dual-use control. Within dual-use discussions there has been a lot of discussion on contextual variations in the application of the "web of prevention" model. However, less discussion exists on the pragmatic aspects of the environments and the possibility that many laboratories are not equipped in a manner similar to those in the UK and USA. In particular, these pragmatic aspects could include poor infrastructural elements such as water and electricity, lack of equipment, lack of regulation, and so forth. While the research conducted in these laboratories may be entirely responsible, it is often difficult to see how scientists in these environments would be able to fulfil some of the role responsibilities which are being attributed to their Western colleagues, and thus to them.

Chapter five investigates how these pragmatic issues influenced discussions on dual-use and dual-use regulation. In particular, combining interviews with

embedded observations the chapter considers a number of key issues including:

- Adequate and focused biosafety and biosecurity measures on a national level
- National support and buy-in for dual-use initiatives
- Regulation of scientific research by the government, and government funding for research
- A developed and functioning research environment
- Structures in place to assist in research, such as waste disposal, energy supply, transport and border controls

It is likely that a better understanding of the differences in working environments will assist in educational materials, codes of conduct, funding and publication requirements making unrealistic demands on scientists. This will prove important not only practically, but also in avoiding disillusionment and confusion amongst the scientists.

# 2.4.3 Fostering Cultures of Dual-Use Awareness

As discussed above, the goal of creating an international culture of awareness and a shared sense of responsibility amongst the science population relies heavily on the establishment of such cultures within laboratories. Currently, the bulk of responsibility for this is delegated to the PIs, on the assumption that it will be transmitted to their staff and students. This model of teaching by example has a strong historical basis in the culture of Western science, and remains the dominant means of introducing the aims and priorities of scientific research to students. Indeed, it remains a powerful approach that has been used to significant effect in teaching students about scientific misconduct and their biorisk responsibilities. In relation to dual-use, however, such an approach requires further examination. Not only does it rely heavily on the buy-in by PIs to the dual-use potential of their research, but also requires that an *ethical* as well as *practical* culture of awareness and responsibility be established within the laboratory. How ethical principles and priorities are transmitted within a laboratory environment remains a significantly under-examined area, and indeed what responsibilities PIs have in relation to this are far from adequately understood.

Such considerations become particularly important when considering how PIs foster cultures of ethical responsibility in environments that diverge from the typical structure of Western laboratories. The traditional "chain of mentorship" comprising of a PI, research scientists, postdoctoral scientists, technicians and students cannot be assumed to exist in all laboratories. Indeed, chapter six examines the current state of many developing countries, where a lack of research scientists and postdocs places a heavy practical mentoring burden on PIs. The chapter examines whether existing dual-use initiatives that emphasise the role of PIs in fostering ethical awareness within laboratories are suitable for such environments.

#### 2.4.4 Concluding Remarks

Current dual-use issues are often presented as problems to be solved, rather than an ethos that needs to be cultivated. Thus, in keeping with the RCR-focus of most ethical education in science, dual-use is becoming associated with role responsibilities for scientists – through their funding applications, publications, ethical reviews and legal responsibilities. It must be questioned whether this movement away from discussions on a global responsibility for dual-use towards these strictly-defined role responsibilities may actually influence capacity building negatively as dual-use bioethics becomes ever more a "bureaucratic task". Nonetheless, the trap has already been laid and is difficult to disarm. By associating dual-use closely with RCR, biosafety and biosecurity, it has necessarily become associated with the ethical approaches advocated by these models. These, I propose, include a focus on avoiding negative behaviour rather than promoting excellence in conduct; of problem solving rather than viewing a global responsibility; of strictly defined ethical principles; lack of awareness of contextual variations in ethical discourse; and a strong belief in the importance and possibility of international harmonisation. All of these issues, as suggested in this chapter, have the potential to undermine efforts to build a global culture of responsibility – particularly amongst scientists not researching in traditional Western environments.

However, such observations are controversial and will benefit from the insights gained from empirical investigations. In the following chapter the research plan for empirically testing these hypotheses is elaborated on in some detail. Furthermore, the sites in which the fieldwork was conducted are introduced in some detail.

# 3. Designing a Research Agenda

A critical examination of the observations made in the previous chapters raises some obvious limitations of purely theoretical analyses of these issues. Firstly, despite my significant experience as a research scientist<sup>60</sup> and the insight that it gave me with regards to these issues, it is unlikely that any theoretical conjectures made about daily research life will be properly informed without empirical research amongst life scientists. Similarly, any speculation made about scientists in developing countries would need to be interrogated by comparative research.

In order to overcome these issues, it was decided that the theoretical issues raised in the previous chapters would be empirically investigated using a range of sociological methodologies. This approach echoes recent trends in bioethics scholarship which are starting to recognise the value of with empirical research (Frith 2012). Indeed, it is possible that utilising a methodology that sees practice as informing theory just as theory informs practice has definite benefits for scholarship. By carefully employing social science methodologies, it has been proposed that "a middle ground between "traditional" applied ethics that builds on abstract, a priori ethical theory, and contextualist, relativist accounts that reject any form of theory (Frith 2012) may be found. In short, a naturalised ethics that sees the importance of both ethical theory and practice, and one that appears ideally placed to address issues of contextuality within ethics.

This chapter describes how the methodologies were developed to empirically investigate the ethical issues identified in chapters one and two. In particular it elaborates on how the fieldsites were chosen, and why a multi-methodological approach involving interviews, focus groups and embedded observations was used.

<sup>&</sup>lt;sup>60</sup> I hold a PhD in cell biology from the University of Cape Town (South Africa) and worked as a postdoctoral scientist at the University of Edinburgh (UK).

# 3.1 Developing a Research Agenda: Identifying Key Questions and Methodologies

Chapter two investigated the development of the dual-use debate in the life sciences, and how a close association with biorisk management and research ethics has significantly shaped contemporary discussions. By carefully unpacking these associations a number of different problems were identified which I proposed could detract from the development of a *"common culture of awareness and a shared sense of responsibility within the global community of life scientists"* (NSABB 2006: 5). This is particularly pertinent when one considers, as discussed in chapter two, the influence that this approach has had on the development of educational initiatives and awareness-raising undertakings. As mentioned, these issues can be broadly grouped under the following headings:

- Tightly bounded content of ethical principles
- Overemphasis on role responsibilities
- Problematic models for fostering cultures of dual-use awareness

How these areas were developed into specific research questions, and methodologies selected to interrogate them is detailed below.

# 3.1.1 Identifying Key Research Questions

Translating theoretical considerations into practical research questions proved to be no easy task. In addition to the obvious complications associated with designing empirical ethics investigations, this project needed to take into account the likelihood that the scientists participating in the fieldwork would have little to no working knowledge of dual-use (as had been suggested by previous studies by Malcolm Dando and Brian Rappert) or received any systematic ethical training. It was decided that the best means of interrogating the three main issues highlighted above would be by examining various issues associated with daily research practices and laboratory structures. In doing this I drew heavily on my existing knowledge and experience in the field. In the end, the research aims were specified in the following way.

The first aim was to investigate the issues relating to the "content" of ethical principles discussed in 1.4.1. While modern ethics – particularly bioethics - often promotes the idea of globally applicable principles that are associated with specific content, there is an emerging area of criticism for this approach. Amongst others, H. T. Engelhardt have proposed that viewing variation in ethical approaches as determined by the context-specific *interpretation* of the principles - and not just the context-specific *application* of them to daily life - may prove important to developing international ethical discussions.

Within the dual-use debate, as discussed in 2.4.1, it is possible that presenting ethical principles underpinning the discussions as having a stable, content may result in many problems for the development of global discourse. In order to address these issues within an empirical study, it was decided that participants would be questioned specifically regarding their understanding and valuation of the control of dual-use as primarily actions to prevent bioterrorism. If they did not see value in the interpretation of dual-use as the misuse of beneficial scientific research by a third person for nefarious means (Miller, 2007), it would be important to determine whether varying interpretations of "beneficence", "non-maleficence", and "harm" contributed to this position.

The second aim, as discussed in section 1.4.2, was to investigate the issues relating to presenting responsibility for broad social issues as (or related to) role responsibilities, and the problems associated with insufficiencies within research environments as barriers to fulfilling these role responsibilities. In order to empirically access this it was decided to spend some time discussing the idea of a "web of prevention" and its associated role responsibilities (discussed in 2.4.2) with participants, and spend some time assessing their views on emerging dual-use controls - as bureaucratic hindrances or value-

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filled interventions. Furthermore, it would be important to determine what sort of research environment they worked in, what sort of daily responsibilities were expected of them.

The final area to be assessed was relating to the relatively little amount of research that has gone into understanding how ethical cultures are developed within laboratories. As discussed in section 1.4.3, the implicit assumption in the ability of a "chain of mentoring" to transmit and foster awareness for the broad social issues associated with science may be difficult. Indeed, in relation to dual-use awareness, as mentioned in 2.4.3, an over-reliance on this model may be detrimental to educational initiatives. Empirically, this would be assessed by examining how scientists, in particular PIs, discuss the ethical and social aspects of their mentoring relationships, and whether they could see a means (and value) of introducing dual-use awareness into the social culture of their laboratory?

As is immediately apparent from such a list of research foci, the selection of methodologies to examine these issues was crucial. In designing a research programme to address these issues, it soon appeared to me that making sole use of one methodological approach might limit the study by overlooking some of the nuances of the problem – particularly relating to the issues linked to the research environment. Thus, it seemed most appropriate to attempt to triangulate methodologies so as to avoid bias as much as possible.

# 3.1.2 Deciding on a Unified Methodological Approach

After careful consideration of the research objectives mentioned above, it was decided that three different sociological methodologies would be used: focus groups, individual interviews and embedded observations. I felt that these three together provided a very strong approach as the results from each would not only inform the other methodologies, but also allow problems within the data to be identified and addressed. The section below briefly summarises some of the

strengths and weaknesses of each approach. Subsequent sections will describe how these methodologies were utilised within this research.

# 3.1.2.1 Focus Groups

Focus groups are traditionally understood to be structured so as to allow a small group of people to collectively discuss a pre-determined set of issues under the guidance of a moderator (Stewart 1992). This provides two main advantages, firstly that they allow people's experiences and opinions to be examined, and the method allows participants to generate personal questions, frames and concepts, and to pursue their own priorities in their own terms and vocabulary (Kitzinger 1999, Rappert 2007). Secondly, focus groups allow examination into the manner in which group interaction produces data and insights that would be less accessible in interviews (Morgan 1998, Rappert 2007).

Using focus groups in my research allowed me two major advantages. Firstly, as in all the fieldsites awareness of dual-use as a concept was non-existent. Furthermore, none of the laboratories had been the subject of any empirical ethics research before. Thus, having a focus group at the beginning of my time at each site allowed a relatively informal and transparent group discussion to occur which minimised the fear (especially in the African laboratories) that I was in some way "assessing" or "investigating" the laboratories. Secondly, as the focus groups kept to a common theme (Bryman 2008), issues arising from the focus groups could later be picked up in individual interviews for further clarification.

In my previous experience as a practicing scientist I was very aware that scientists are not only extremely busy during the day, but also generally do not welcome taking time out of their working day for "non-scientific matters". As the focus groups were voluntary, I was conscious of the possibility that I would

struggle to recruit volunteers "off the cuff"<sup>61</sup>. I therefore decided that the best approach would be to make use of an existing structure within the life sciences - the journal club. This predetermined time slot would therefore already be accounted for by all the scientists in the laboratory, and also had the further benefit of being a space in which discussion was traditionally encouraged.

In order to further exploit the structures of the journal club, I pre-circulated a scientific paper – one of the typical "experiments of concern" - as a case study for discussion. I found that this structure worked very well for a number of reasons. Firstly, being within a journal club structure scientists were aware of what was expected of them (to critically engage with and comment on the paper), which might not have been possible by simply inviting them to a "focus group". Secondly, pre-circulating the paper gave the participants time to reflect on it (and google more information about it, as was often the case). Due to the low level of prior dual-use awareness, this was a useful means of ensuring coherent discussion.

This methodology provided an excellent means of accessing group reactions to the concept of dual-use at the fieldsites. It allowed the scientists to interact and discuss a topic that many are not familiar with on their own terms, and thus gave insight into how the groups of scientists constructed an understanding of a novel concept. Often during the focus groups (which of course was absent in individual interviews) participants probed each other's reasons for holding a specific point of view, and raised my attention to certain issues that would otherwise not have appeared of significant importance due to my unfamiliarity with the specific fieldsites. Furthermore, in all the focus groups, the participants brought to the fore issues that they deemed important and significant. This varied considerably between the different fieldsites and proved a vital element of the subsequent analyses.

<sup>&</sup>lt;sup>61</sup> Indeed, at the first fieldsite I did try to invite volunteers to sign up for a "focus group" after I had given my introductory seminar. I only got one volunteer this way.

Moreover, during the focus groups it was also noted that this methodology provided an excellent means of triangulating the impact of the physical environment on these discussions. Some of the participants were highly vocal about aspects of their physical and regulatory environment. Thus, the focus group not only provided an opportunity to observe them raise these issues amongst their peers, but also to assess their peers' reactions to their comments. All in all, this allowed me to develop a better understanding of the group's perceptions of their physical and regulatory environments.

Despite the success of the focus groups at the fieldsites, and the considerable discussion that they stimulated amongst the participants, the limitations of focus groups cannot be overlooked. Indeed, previous studies have drawn attention to their lack statistical generalizability, and the significant resource demands - especially through the time involvement of the researcher in preparing, conducting and analyzing the focus group (Rappert 2007). These problems were obviously present in my research as well, and were addressed by ensuring that the information from the focus group was revisited during individual interviews so that the reliability of the data could be assessed.

Another characteristic of focus groups that has often been noted is that group interview settings can both produce conformity and discourage openness (Kitzinger 1994, Rappert 2007). Indeed, in some focus groups – particularly in Kenya – a strong laboratory hierarchy did seem to prevent unanimous participation in the discussion. Being aware of these limitations during the process of data collection, and ensuring that the results obtained were triangulated with interviews and informal discussions during observations hopefully ameliorated any bias that may have occurred in the data.

#### 3.1.2.2 Interviews

Frey and Oishi defined an interview<sup>62</sup> as a "purposeful conversation in which one person asks prepared questions (interviewer) and another answers them (respondent)" (Frey 1995). This allows information to be gathered which could potentially facilitate further research using alternative methods such as observations. Individual semi-structured interviews played a significant part in this research and allowed me "one to one" time with Pls, researchers, technicians, students and various administrative persons involved in research. These interviews covered a list of topics concerning dual-use, their daily research, and their perceptions of research in their laboratory and national context (detailed later on in this chapter). As one of the important foci of this research was to gauge how and why scientists engage with the concept of dualuse, and what they used in their environment as positive or negative reinforcement, allowing the interviewees to exploit the element of freedom in narrative that semi-structured interviews facilitated (in comparison to structured) played a vital role in developing an understanding of daily research at the fieldsites.

Of course, information gained from semi-structured interviews is subject to a number of issues. In particular there is a widespread recognition of the influence of the interviewer themselves on the interview. I was highly aware of this during the fieldwork and endeavoured to keep my participation in the interviews to a minimum. Luckily, it would appear that the topic, combined with my perceived "credibility" as an experienced life science researcher<sup>63</sup> meant that most participants were highly vocal and my participation or prompting was low. Although a time consuming methodology in both data collection and

<sup>&</sup>lt;sup>62</sup> Interviews fall into two categories: structured and unstructured, depending on the manner in which questioning is approached. Unstructured interviews, as are used in this project, do not utilize a standard set of questions which allows fieldworkers to deal with the topics of interest in any order and to phrase questions in the manner which they deem best Nichols, P. (1991). Social Survey Methods. Oxford.

<sup>.</sup> This method allows a broad range of questions to be asked in an order determined by the manner in which the interview progresses.

<sup>&</sup>lt;sup>63</sup> Many of the participants – particularly at the African fieldsites made comments to the effect that I "understood" what they were talking about because I was previously a scientist, or that I was "on their side" because I knew what it was like to do life science research in Africa.

analysis individual interviews formed the bulk of the data collected at each fieldsite. They proved very successful in allowing the individual participants space to develop their own ideas about dual-use, and to link it to their personal experiences as researchers within a specific context.

#### 3.1.2.3 Embedded Research

Because of my personal awareness of the variations in physical research environments between laboratories, and my belief in the influence that the environment has on the development of ethical dialogues, I also decided to further inform the participant data with some unobtrusive observations. In contrast to most other embedded sociology research conducted within laboratories (such as those by Bruno Latour and Sharon Traweek), I decided to play to my strengths as a previous life science researcher and combined participant observations with a critical analysis of the physical laboratory environment and how research was conducted within these environments.

In particular, I undertook to examine and understand the systemic environment of the research – the social, regulatory and physical environment that governed the daily practices. This led me to become interested in seemingly innocuous details of daily research, such as waste disposal, which nonetheless proved very fruitful - especially (as will be shown in chapter five) when analysed in conjunction with the other data. Thus, these observations allowed me to build up a holistic picture of daily research within these fieldsites that significantly informed my interpretations of the data arising from the focus groups and interviews.

At each fieldsite, the process of this embedded research varied according to the availability, access and interest of the participants and included shadowing of scientists during experiments, personal laboratory assessments, and formal laboratory tours. Nonetheless, within each fieldsite I attempted to examine a

"check list" of environmental elements as a minimum standard of observation (as will be detailed below). Being allowed to integrate myself in the research environment proved a significant asset for the subsequent analysis of my data.

# 3.2 Developing a Research Agenda: Gaining Access

As mentioned above, from the earliest days of the project development it was apparent that this research would benefit from a comparative approach involving laboratories in a number of developed and developing countries. When selecting laboratories as fieldsites, however, a number of different issues had to be confronted. How the fieldsites used in this project came to be involved are detailed below.

# 3.2.1 Identifying a Unifying Research Stream

One of the most important aspects of developing the research protocol was an awareness of the dangers of over-generalisation, of which the concepts of "life scientists" and "developing countries" are prime examples. Indeed, research facilities have significant similarities and differences on institutional, national, regional and international levels, while the different disciplines within the life sciences show considerable differences in both research cultures and methodologies. I decided that it would therefore be important to limit my fieldwork to specific regions and discipline, so as to best exploit the comparative nature of the study.

# 3.2.1.1 Deciding on a Region of Interest

The decision to consider laboratories in sub-Saharan Africa and in the UK as examples of developing and developed countries was largely motivated by my own previous experiences as a researcher in South Africa and Scotland. In choosing these areas I gained significant advantage in prior knowledge of how research is conducted in these regions. Nonetheless, the choice of sub-Saharan Africa offered a number of other advantages as a means of studying developing countries, and the "characteristic problems" that arise in these settings. Some of these issues are briefly detailed below.

Historically (with the exception of South Africa) national institutions for higher education in sub-Saharan Africa have been not only small but also *"undifferentiated"*, meaning that a small number of publicly funded institutions have been tasked with discharging a wide range of different academic, teaching, research and support functions (Fine 2007). Furthermore, any growth has been reflected principally in rapid expansion of undergraduate education, rather than a deepening of the overall system through greater institutional specialization (Fine 2007: 1).

With the exception of South Africa, countries in sub-Saharan Africa invest less than 0.3% of the GDP into research and development (R&D) (COHRED 2010)<sup>64</sup>. Thus, in most cases research projects tend to be *financed by external sources*, and are usually focused on condition-specific or vertical programmes. For example, within the research on neglected disease drug development, public-private partnerships account for some 75% of research in sub-Saharan Africa (COHRED 2010). Current research of global trends suggests that national systems of higher education in the region will remain sub-optimal in size without considerable funding inputs or restructuring.

Many sub-Saharan African institutions have also been struggling to overcome *legacies of the past*, which include poor secondary school teaching, shortage of staff, an ageing generation of academics. This means that new scholars will often lack experienced mentors and increased teaching demands, as well as a spotty record for designing appropriate modalities for investing in both research and higher education (Fine 2007: 3). Additional issues that hamper development of these institutions are listed below and afterwards discussed in further detail.

<sup>&</sup>lt;sup>64</sup> It must be highlighted that R&D does not necessarily include basic science research.

- Small, undifferentiated institutions with little collaboration
- Lack of funding and lack of effective mechanisms for utilization of funds
- High teaching burden
- Lack of experienced mentors due to brain-drain
- History of poor investment in higher education and research
- Lack of buy-in by institutions for new initiatives (such as centres of excellence)
- Need for networking and networks
- Corruption, mismanagement and institutional rigidity
- Lack of governmental support, funding and control
- Lack of vetted information about possible collaborators and institutions
- Need for strong administrative and managerial skills
- Inadequate resources and allocation thereof

Particularly in relation to this project, African science, as with many other developing countries, has played a minor role in the development of the concept of dual-use issues in the life sciences. Although the biological weapons programme developed by the South African Apartheid government has received considerable attention in relation to WMD development and control (Atlas 2006, Miller 2007), other African countries are rarely mentioned in discussions. However, despite the absence of dual-use discussions about, or within, Africa, the associated issues of biosafety and biosecurity are increasingly examined, as signified by the recent development of many biological safety and security regulation and networks within and between African countries.

Nonetheless, by and large, interpretations of biosafety and biosecurity issues in Africa have focused mainly on food security and production, and existing discussions have been compounded by poor infrastructure and lack of buy from national governments, unfamiliarity with concepts and differing priorities and insufficient legal structures to ensure the enforcement of international standards<sup>65</sup>.

In comparison, life science research in the UK (as a good example of a developed country) is well established. High levels of government funding, a comprehensive regulatory system, together with private investment and support have contributed towards making the UK a world leader in many areas of life science research. Furthermore the UK, together with the USA, Australia and some EU countries, have taken the lead in addressing the dual-use potential of research conducted within their borders and the reasons for concern (as discussed in chapter two).

Selecting laboratories from countries within the sub-Saharan Africa region and using the UK as a control country thus provided a good opportunity to investigate how the dual-use debate travels outside a strong Western/developed environment, and whether systemic issues relating to research (such as low funding, lack of mentorship, poor administration and other topics mentioned above) influence how this debate is internalized by local communities of scientists.

<sup>&</sup>lt;sup>65</sup> These issues are taken from a report of a meeting held on November 5-6, 2008, in Bethesda, Maryland, hosted by the National Science Advisory Board for Biosecurity and co-sponsored by the WHO and the US government. NSABB Meeting report 2009, "Sustaining Progress in the Life Sciences: Strategies for Managing Dual Use Research of Concern – Progress at the International Level". *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,* vol. 7(1), pp. 93 – 100.

# 3.2.1.2 Deciding on a Discipline

The life sciences as a field of research involve a considerable number of disciplines and sub-disciplines, all of which utilize methodologies specific to their areas of investigation. Although there is a temptation to view these different disciplines as involving the same research practices and governed by the similar research cultures, such oversimplifications are often at odds with what is happening "on the ground". Recently, a number of different reports, such as the Lemon-Relman, have commented on the difference between disciplines both on a practical level (as in differing methodologies and research foci), but also as research cultures.

In order to avoid unintentionally biasing the research results with disciplinedependent differences, I decided that all the laboratories to be visited in the course of the fieldwork would share a single research focus. As some of the most visible research occurring in sub-Saharan Africa involves HIV/AIDS I decided that all the fieldsites would be involved in some aspect of HIV vaccine development. Selecting this field of research proved advantageous for a number of different reasons.

A primary consideration was that a number of international research networks exist which unite laboratories concerned with HIV vaccine development. The International AIDS Vaccine Initiative (IAVI) is one of the most influential ones<sup>66</sup>, and all laboratories selected were associated with this research network in some capacity. It was initially thought that this network would provide an "ethical baseline" from which to examine variations in the ethical cultures of research communities, however, this approach did not prove fruitful. Nonetheless, the IAVI network proved invaluable in identifying fieldsites and getting access.

<sup>&</sup>lt;sup>66</sup> <u>http://www.iavi.org/Pages/home.aspx</u> (accessed 11/05/2011)

Secondly, due to the overwhelming health burden that HIV represents to sub-Saharan African countries, it appeared likely that any government funding for basic research would likely be directed in these areas. This was an important consideration as I had hoped to identify laboratories that were not entirely funded by foreign grants. I anticipated that laboratories which were wholly funded by foreign grants would be highly regulated according to the ethical requirements of these grants, and therefore probably be more in line with the ethical priorities of the developed countries. As it happens, the laboratories selected had a range of different funding structures, which provided some interesting elements of comparison that are discussed in chapter five.

A final consideration was that vaccine development, as discussed in section 2.1.3, is associated with the "experiments of concern" identified in the Fink Report. Thus, I hoped that this link between the current dual-use literature and the research being conducted within the fieldwork sites would provide the participants with a more direct access to the concept than would have been the case in many other laboratories. This decision had an interesting corollary that became apparent during the course of my fieldwork. In all but one of the fieldsites I was requested to re-run focus and discussion groups for students and members of staff not directly affiliated to the laboratories I was visiting. In many cases this was due to word-of-mouth discussion by my study participants. These additional focus groups comprised of a range of scientists working instead in cell biology, genetics and biochemistry. During these groups I did notice that initial hesitations to the concept of dual-use were amplified in these groups, and that a number of misunderstandings regarding different methodologies and research foci were present. This will be discussed further in chapter four.

An additional benefit of selecting HIV vaccine development as the focus of the study was that it has not been explored in any significant manner by current dual-use studies. Thus, any reflections that might arise regarding dual-use concerns in HIV research might contribute novel insights into current debates.

#### 3.2.2 Narrowing it Down: Finding the Fieldsites

The four African laboratories selected represented four of the main African research laboratories in the IAVI network. Interestingly, the selection comprised of two laboratories mainly engaged in basic science research: the two South African laboratories (SA1 and SA2), and two primarily clinical trial laboratories in Kenya and Uganda (KY1 and UG1). The UK laboratory (UK1) was selected as a means of gathering comparative data. The order of visiting was determined by the availability of the institutions, and went as follows: SA1, UG1, KY1, SA2, UK1.

As mentioned in section 3.1.2.3, accessing the data arising from this fieldwork requires an understanding of the different fieldsites that were visited. Although elements of the regulatory-physical environment are continually referred to in the analysis chapters four to six, I believe it is helpful to introduce each site briefly in its entirety prior to these chapters. The sections below attempt to provide a "shapshot" of my perceptions and understanding of each fieldsite – while also focusing on specific elements that will prove important to the subsequent chapters, namely funding, waste disposal, laboratory facilities and regulations, as well as staff structures.

Although complete confidentiality was promised to all study participants, similar confidentiality was not promised to the institutions that I visited. Thus, although every effort has been made to remove identifying features from these descriptions, it is likely that some of the sites will still be recognisable to those who are familiar with the field of HIV vaccine research. This is unfortunate, however it is hoped that the value of the data presented below and in the fieldwork chapters will justify the presence of any identifiers.

#### 3.2.2.1 <u>SA1</u>

This laboratory is based in a recently opened, dedicated institute for infectious disease research. Within the institution, research is centralized on HIV/AIDS and tuberculosis and other locally relevant non-communicable diseases. The Health Sciences Faculty of the university in which this institute is based has an outstanding international reputation and a distinguished tradition of research in the biomedical, clinical and public health fields.

According to their mission statement, the institute explicitly prioritises a multidisciplinary approach to disease and aims to avoid artificial divides of disciplines, faculties and institutions. Instead national and international partnerships and collaborations are actively pursued in the interests of making an impact on the health crises threatening Africa. The main objective of the institute is therefore to translate or apply insights and discoveries generated through basic scientific enquiry to the treatment or prevention of disease with new drugs or vaccines, and to apply scientific discovery from the lab bench to the bedside and ultimately to the community.

There are more than 25 groups at the institute (including cell biology, immunology, human genetics, microbiology and molecular medicine), each of which is led by a PI who sources operational funds and equipment for their projects from local and international funding agencies. Many of the members are Wellcome Trust International Senior Research Fellows, or researchers active within well-established research units set up by the SA Medical Research Council at the university, or groups supported by the South African AIDS Vaccine Initiative or the Areas Global TB Vaccine Initiative. Four research units of the MRC are housed directly in the institute while others are in nearby buildings.

There are five full associates at the institute conducting HIV research, and I visited the group of the one most involved in the HIV vaccine initiative. Her research interests centre on HIV diversity and pathogenesis, and is involved in the characterisation of HIV transmission and the evolution of recently transmitted viruses; the elucidation of viral escape from immune pressure; the impact of diversity on pathogenesis; as well as the implications of diversity on vaccine design.

The institute was created specifically to facilitate interdisciplinary research and pooling of physical resources. The central atrium contains a coffee shop and a number of seating areas, and the laboratories (built on two quadrangles) are largely open-plan. However, space is at a premium in the building, and office-and bench-space tightly regulated. Nonetheless, the as a flagship institute of the university, it has been generously funded both locally and internationally and many of the facilities and equipment are state-of-the-art.

In my opinion, however, despite the emphasis on interdisciplinary flow, the structure of the building does not inspire communication. This problem was reflected in many of the conversations with scientists working in the institute (as reported later) – that the research culture tended to remain group-based and more insular. This was reflected in some of the practical difficulties I experienced during my fieldwork there. Although there was a central administration and the bureaucratic details were well handled, there didn't seem to be much communication between the admin and the staff, and between the PIs and the other researchers. Many contacts made were through previous acquaintances and not through the expected channels. In addition, many of the PIs did not answer emails or schedule appointments, which made organizing observations and interviews with their staff difficult.

In contrast, however, the student and postdoc body was very active and organized many different activities in the centre, including the journal clubs and discussion groups. These occurred through the different disciplines, however, and there were little interactions between the different research groups apart from the centre seminars which did not have a high level of attendance (as far as I observed).

As a large amount of equipment was shared between research groups, SOPs are present for the shared equipment. Other protocols are passed between members of a group and/or laboratory. Students are taught rudimentary laboratory work during their undergraduate and honours years, and it is assumed that they are competent in laboratory basics when they join as postgraduate students. Most students utilize a range of techniques, and one-on-one teaching of new techniques (by PI, tech or other student) was common. Pls do not do a lot of work in the laboratory and it is usually technicians that oversee work in the laboratory. Interestingly, however, despite the PIs tending to have high numbers of postgraduate students to supervise, the teaching burden for formal lectures did not appear too high.

The institute has a considerable number of technicians and cleaning staff that maintain the laboratory. Glassware is centrally washed and autoclaved. Students are responsible for their own research and specific ordering, although orders for general consumables were submitted by a senior technician. The university has an incinerator for laboratory and clinical waste, which is bagged separately according to contents and disposed accordingly. South Africa has a reasonable system for disposal of laboratory waste that is regulated by the government<sup>67</sup>.

Within each research group, individual results were shown to PI at individual meetings (regularity of meeting at discretion of PI). They may also be shared during group meetings, although it is often only synopsis of results that gets shared, or specific problems. Within the centre, however, researchers only present once at an annual seminar presentation.

<sup>&</sup>lt;sup>67</sup> This is based on the conversations that I had with laboratory technicians and related staff, who showed me government regulations and guidelines for waste disposal.

Internet access is adequate and facilitates all necessary communication and research. All students and staff have access to a personal computer and printing facilities. The library holds a small number of relevant print journals but subscribes to a range of electronic journals. Access to journals was often cited as a drawback by many of the participants.

# 3.2.2.2 <u>KY1</u>

The Kenyan institute I visited was based at the Department of Medical Microbiology in a well-known university. It occupies two floors in the health sciences building of the medical campus. The university buildings are relatively old, but well maintained (with the exception of roads).

Access to the medical campus was not tightly controlled, and although there was a guard on the gate there was no obvious access control. Access to the institute was through swipe card access on the main doors. Laboratories inside the facilities had swipe access on the doors, however these were invariably open. On the lower floor there are three laboratories: serology, peripheral blood mononuclear cells (PBMC) and cell culture (there is also a small flow cytometry room). In addition, there are facilities for trial volunteers consisting of exam rooms, a waiting room and a doctors' common room. There are also offices for the secretary, the head of laboratory services and the medical manager.

Staff consisted of a limited number of academics, and the majority is comprised of laboratory technicians, clinicians, nurses and administrative staff. The institute did not host many students, and although there were two MSc students working in the serology lab, the bulk of their projects were based at another research facility. There was one member of staff who had recently completed his PhD and was about to start a postdoc, although he was to be primarily employed by a foreign university. The majority of the staff is based at the
institute, but there is a satellite site for sample collection about 10kms away. Samples collected here are transported to institute daily and processed. Interestingly, all samples were ultimately shipped to the USA for storage.

As a relatively autonomous body with foreign funding, the institute did not appear to interact with the rest of the university much. Within the institute laboratory meetings were held weekly. During this meeting (which is of minimum 2.5 hours in duration) aspects of each research project were discussed in a formal manner and carefully minuted. Such an approach appeared appropriate as most of the projects involved many members of the centre. Each lead researcher/technician was called upon to provide a brief update on their work – mainly on clinical trial progress. At the end of the meeting there was a time for general issues and problems. During this time problems with customs delays, shipping of samples, keeping track of volunteers and the possibility for double enrolment in trials (and thus the need to identify volunteers) were discussed.

A general meeting with all the staff (ie. including the satellite sites) was held once a month. In this meeting general administrative and running issues were discussed. The journal club follows these meeting, however the ones attended were project summaries of existing research, and did not include discussion of peer reviewed articles or research.

Most of the work done at the institute was for IAVI multi-site studies or IAVIinitiated studies. Thus most of the work done was governed by SOPs that were generated off site (usually USA or UK). It was mentioned that a certain leeway was allowed for situational adaptation of protocols (mainly with regards to volunteer-related SOPs). However, the institute had a designated quality control officer who was responsible for ensuring compliance with SOPs. It must be noted that the institute was essentially a diagnostic facility with little independent primary research. Work at the institute was controlled by three "line managers": laboratory, medical and administrative. Staff working under the line managers work in very specific areas, such as cell separation, plasma analysis and so forth.

Nonetheless, despite the SOPs, in my opinion the level of personal protective equipment (PPE) was lower than in other sites visited. Although gloves and lab coats were commonly utilized, other PPE options were not observed. Furthermore, designated task space and adequate signage was less obvious than in other laboratories. Waste in the department was colour bagged according to common practice. Furthermore it was noticed that in serology pipettes were disinfected in bleach prior to disposal (although this practice was not observed in all areas of the department). Waste disposal was contracted to an external company for incineration off site.

Interestingly, I noticed that yellow (biological waste) and black (general waste) bags were stored in one pile in an open site behind the hospital without access control or warning labels. It was also noticed that the road leading out of this dumping site was littered with used syringes and tubes, suggesting that at least one bag had become undone<sup>68</sup>.

The results generated from the samples are predominantly paper (backed up by photocopies) which are stored in files inside the labs. It was stated that there was no capacity for electronic backups. This seemed odd, as most of the machines were automated and the computers and internet facilities were adequate (although not all staff had access to a personal computer). Clinicians had to physically enter the labs in order to check on results.

<sup>&</sup>lt;sup>68</sup> This observation was similar to those made at KEMRI (Kenya Medical Research Institute) in 2010.

#### 3.2.2.3 <u>UG1</u>

The Ugandan institute I visited was part of a research facility that had been developed at the request from the Ugandan Government by the British Government for collaboration on the research of HIV infection and AIDS. The resulting facility is the product of a multinational research consortium and is heavily supported (financially and with researchers) by UK and USA institutions. Although it has a working agreement with the government and a mandate to conduct multidisciplinary research on HIV disease and related infections to facilitate their control in Uganda and elsewhere in Africa, the Ugandan government does not contribute financial support to the facility. Therefore, the facility represents a relatively autonomous research institution that is nonetheless well established in the local community and involved in the formulation of health policies both in Uganda and elsewhere. Importantly, the facility provides infrastructural support to the health services in the areas in which they work, and is a key facilitator in building research capacity in East Africa.

The facility is a closed site consisting of a number of buildings and laboratories, which are compact yet do not appear overcrowded. There seems to be a considerable institute identity, with a friendly and less formal attitude being taken between staff members. In my fieldwork I visited the Basic Sciences Research Programme, a department of around 20 researchers, students and technicians. As the facility only provides laboratory placements, and does not offer teaching, the students are integrated well into the department and conduct independent research. The Basic Science Programme conducts research in virology, immunology, molecular biology and genetics with the aim of developing an effective HIV vaccine; and improving the treatment of HIV infected patients. To achieve these objectives, the Programme makes use of the well-established cohorts and clinical trials run by the facility in Uganda<sup>69</sup>. Over recent years, their research has described the molecular epidemiology of HIV-1 within the facility surveillance area in south west Uganda.

<sup>&</sup>lt;sup>69</sup> This information is from the website www.mrcuganda.org/BasicScience1.html

<sup>147</sup> 

The laboratories are well equipped and assays include elispot, viral sequencing with cloning capability, flow-cytometry with an 18-colour LSRII cytometer, culture elispot, virus neutralization assays and others. They also plan to introduce single genome amplification and microarray in the near future. The work done by the department adheres to Good Clinical Laboratory Practice standards; and studies conducted in the context of international collaborations are regularly subject to external monitoring.

Nonetheless, the laboratories are not extensive and space appears to be at more of a premium. The equipment, while often not state-of-the-art, is most adequate and well maintained. As a considerable amount of facility's research involves clinical trials, the basic sciences department shares their building with the clinical laboratory services department. A large common room is well utilized by all staff in the building.

Lab meetings are conducted every week and are attended by the entire basic science division. In the meeting a brief synopsis of each research project progress is given by the principle scientist. General topics such as budget and publications are then discussed. Finally, laboratory maintenance issues are discussed in some detail.

It was important to note that the infrastructure of the town in which the facility was situated was not extensive, and to this end the facility appeared to operate as a relatively autonomous unit making use of generators, internet servers and internal waste disposal services to ensure daily laboratory functioning.

#### 3.2.2.4 <u>SA2</u>

The second fieldsite I visited in South Africa was a unit based in the Department of Molecular Medicine and Haematology at another prestigious university. The unit is relatively small and comprises of 20 members including clinicians. The basic science researchers in this unit are comprised of two PIs, 1 postdoc and 13 graduate students. In addition, there is a laboratory manager and two technicians.

The unit focuses on advanced gene therapy for treatment against viral infections, including hepatitis B, HIV and hemorrhagic fevers<sup>70</sup>. In particular, the department specializes in RNA interference techniques, also using modern molecular research techniques including gene transfer to mammalian cells, as well as the use of lipoplex and recombinant viral vectors. The predominant research is conducted using cell culture, however murine animal models are also used. Within the laboratory there was a good amount of up-to-date equipment, and adequate facilities for all the research being undertaken.

The unit has been the recipient of considerable financial support both from the South African government as well as international donors, and maintains a strong network of international collaboration. Students were also actively encouraged to utilize these international contacts and the unit had a strong tradition of conference attendance and international exposure for the students.

The unit is located on the university's medical campus. This is a tightly controlled campus with entrance security and card-dependent access to various areas of the compound. The unit occupies space within the Department of Molecular Medicine and Haematology, and comprises of a number of shared offices (apart from the HoD), laboratories and various storage and wash-up

<sup>&</sup>lt;sup>70</sup> It must be noted that the majority of the work on haemorrhagic fevers was on a molecular level and did not involve work with the pathogens. However, there were future plans to conduct *in vivo* experiments that would occur off-site at the dedicated BSL-4 facility run as a government research institute.

areas. Space was at a premium in this department and regularly mentioned by all members of the unit. Nonetheless, all staff and students had access to their own desk, computer or laptop, internet and printing facilities.

Most of the laboratory tasks were shared amongst the members of the units, however ordering was processed through the laboratory manager. Wash-up and waste disposal was handled by the technicians and, in my opinion, was well executed. Waste was separated in the laboratory, bagged and disposed using strict guidelines. As at the SA1 site, off-site waste disposal was handled by a government-approved company according to strict regulations.

All members of the laboratory appeared to have a high level of personal autonomy in their research that was mirrored by their awareness of the regulations surrounding their research. Interesting, as part of the postgraduate programme, all students were required to develop and submit the ethics approval application for their research and many commented on the insights that this process had given them regarding their research.

Laboratory meetings occurred weekly, as did journal clubs. In addition, the PIs sought to have individual meetings with their students to discuss their research results at length. In the laboratory meetings and journal clubs that I attended I observed a high level of mutual interaction between staff and students, and robust discussion occurred seemingly without hierarchical considerations.

Conducting fieldwork at the unit was relatively straight forward, no doubt in part due to a previous connection that I had with one of the PIs. At the time of my arrival the information sheets had been circulated and the PI had attempted to inform his staff as to the purpose of my visit. Nonetheless, getting the students to commit to interview appointments remained a challenge (as indeed it was in all the sites). All in all, however, the participants in this site were extremely helpful and well informed.

#### 3.2.2.5 UK1

The UK group that I visited was conducted mucosal infection and immunity research at a prestigious university. It comprises of 25 researchers, of which there are 3PIs, 6 postdoc fellows, 8 research assistants, 2 clinical fellows and 2 PhD students. The group also has a dedicated operations manager, a laboratory manager and a general technician. The group is headed by an internationally-recognized expert in HIV research.

The group focuses on the mucosal transmission of HIV and the development of novel preventative strategies appropriate to developing work settings. In particular, much of its research focuses on the preclinical identification, development and selection of microbicide and vaccine candidates prior to clinical efficacy trials. The research conducted by the group is internationally collaborative, with many connections to other research groups and networks.

A number of national and international funders are involved with the group, although many of the individual researchers have to source their own funding for their research. This was made apparent to me by the imminent departure of my primary contact due to an inability to secure funding to support his research at the group. The high level of pressure on securing funding, and the competition to do so, was commented on a number of times by participants. In addition, despite some of the senior postdoc fellows being well-recognised scientists, it appeared that there was a shortage of permanent positions at the university – a situation that was regularly commented on by many participants.

The group occupied the majority of a floor in an accessed controlled building (although access to the campus was not controlled), however space was at a considerable premium. The majority of staff shared one large office, although the HoD, lab manager and operations manager had separate offices. The laboratories were well equipped and appeared to contain a high standard of

equipment. These laboratories were a combination of BSL-1 and BSL-2, and access to the BSL-2 units were controlled.

Predictably, due to the strong regulatory tradition in the UK, the research was subject to considerable regulatory demands, which it was the duty of the laboratory manager to enforce. These included compulsory orientation and training of new staff, regular safety and security assessments, protocol review and similar activities. Most of the staff appeared well aware of their regulatory obligations, and the manager mentioned that general compliance was high.

The group met weekly for a journal club as well as a separate laboratory meeting. In the laboratory meeting one individual took a turn to present their research. These meetings appeared well attended and highly interactive, with little hierarchical limitations being apparent.

Once I had established contact with an interested individual, the access to the site was relatively straight forward (although getting in touch with the correct contact person proved a rather elaborate process of referrals), and every effort was made to accommodate me. In the interviews and focus groups the staff were very interactive. Interestingly, my visit coincided with the launch of an ethics programme aimed at undergraduates. This is an innovative and extensive ethics education scheme that involves undergraduate students, experts and postgraduate/staff facilitators. Three of the participants were involved in this project (in some capacity), which may have primed the site for ethical discussion.

## 3.3 Gaining Access to Fieldsites

Not wholly unexpectedly, and no doubt due to the vastly different research setups, cultures and foci in each site, there were a number of complicating factors in gaining access to the fieldsites. Firstly, there appeared to be considerable ambiguity regarding my role as a social science researcher investigating scientific practices. In spite of having circulated an information sheet regarding my project and the purpose of my visit at each site prior to my arrival, many of participants mentioned that they had misunderstood the purpose of my research before speaking directly to me. This situation was no doubt exacerbated at the KY1 and UG1 sites by my "contact person" not having had any previous experience in social science research.

It did appear that this confusion was not due to an ineffective information sheet, but rather due to the participant's lack of previous experience with social science research. Particularly in Kenya and Uganda there was considerable confusion amongst the staff regarding my role in research and the purpose of my visit, and it is my opinion that the particular confusion was due to the lack of awareness of the scope of social science research in these countries.

Further confusion arose as a result of a misunderstanding of my role as an ethicist not directly involved in research on clinical ethics or research misconduct. Many participants were initially under the impression that I was conducting an ethical audit of their facility and thus were hesitant to discuss negative aspects of their research. However, through continually raising attention to the aims and expected outcomes of my project I managed to wean them away from this perception.

Both misunderstandings have impressed on me the need to be extremely explicit regarding the methodology and expected outcomes of research. Within Africa the relative lack of social science research conducted on the life sciences outside the realm of clinical research and trials makes it vital that the aims and objectives of social science research are properly addressed by each researcher. Some more considerations are discussed below.

#### 3.3.1 Ethical Approval

As the project involved both obtrusive and unobtrusive methodologies, ethical approval was necessary from the University of Exeter. Prior to contacting any of the fieldsites a project synopsis was submitted to the College of Social Science and International Studies Ethics Committee for approval. This approval (appendix 1) was granted without amendments and duly included the information pack sent out to prospective fieldsites.

In each fieldsite the head of department or principle investigator was initially contacted with this project information and fieldwork proposal. As two of the fieldsites had very little information on their websites, subsequent ethics arrangements and contacts were made following the advice and approval of these key contact people.

It was extremely interesting to note that in no two fieldsites was the ethics approval process the same. No doubt arising from the confusion of wanting to do *social science* research on *life scientists*, and the relative dearth of sciencerelated social science research in Africa beyond those focusing on clinical investigations, most of the fieldsites seemed ill equipped to cope with my ethical application.

The SA2 site, although initially requesting that I make an application to the health science ethics committee amended their request after further discussion and allowed my application to be made to the social science ethics committee. Out of the four sub-Saharan African fieldsites this was the only one that

appeared to have a working ethics committee devoted to assessing social science research. Once the confusion regarding the research focus had been cleared up the application went through with no complications.

The SA1 site requested that I submit my proposal to the health science ethics committee as the research was to be conducted in the faculty under their jurisdiction. Despite the relative inapplicability of the form to my research application, the form contained "opt out" conditions where the questions were inapplicable. It would appear that the ethics committee had experience dealing with social science requests, as the application was once again accepted without amendment.

In both the KY1 and UK1 sites, despite repeated queries on my behalf, I was granted access to the fieldsites solely on the approval of the head of department. Both of them, interestingly, suggested that as I was interviewing their staff with informed consent that access to the facility was the only permission necessary.

Unfortunately, at the UG1 site, the process of ethics approval significantly complicated my research and negatively impacted on my research experience. I received initial approval by the head of department upon the receipt of all project documents, and consequently started my research interviews and focus group. Half way through my research there, however, I presented a synopsis of my project to the entire facility that provoked an uproar. It appeared that different members of staff had different opinions regarding the level of ethics approval needed for my project. In order to appease them I submitted an application to their facility research ethics committee however, no doubt due to intradepartmental politics, my application was repeatedly returned and requests made for further information. As a result of this, I was unable to complete the desired number of interviews and focus groups, and spent the rest of my time at the facility waiting for ethical approval. Retrospective approval for the research already conducted was granted almost a year after my return to the UK.

Despite all these complications, every attempt was made to comply with the ethical standards of the University of Exeter and the facilities being visited. If nothing else, the continual struggle to gain ethics approval for my project from the different fieldsites ensured that the ethical aspects of my empirical research were always at the front of my mind.

#### 3.3.2 Getting Endorsement from Research Communities

It was rightly assumed that in most cases the scientists at the fieldsites had not heard of the concept of dual-use – and indeed received little formal ethical training. Furthermore, for many of the participants it was the first time that a social scientist had visited the laboratory. These two complications make a level of distrust and misunderstanding from the participants a hazard.

In order to maximize awareness about my purpose for visiting the laboratories, I therefore decided to utilize a number of strategies to make myself more visible. Firstly, at the start of research at each fieldsite, I gave an introductory seminar to explain the basic concepts of dual-use and the purpose of the research. This introduced the basics of the concept of dual-use, and explicitly outlined the purpose of the project. These seminars were always given during a designated seminar slot, which resulted in good participation. The seminar usually (depending on the time allocated) ran for 40 minutes, and 20 minutes was dedicated to questions from the audience. The seminar was recorded to capture the questions of the audience and their initial response to the concept of dual-use.

I also prepared an information sheet (appendix 2) for all members of the laboratory that I requested to be circulated prior to my arrival. This information sheet (identical to that forwarded with consent forms) briefly outlined the purposes of my visit, and contained my contact details.

Introducing the participants to the concept of dual-use prior to the fieldwork raised obvious issues of relating to the pre-exposure of the study participants to the subject of research. By circulating information sheets and conducting the introductory seminar, participants were obviously exposed to a specific interpretation of my research, and the topic of dual-use. Nonetheless, I reasoned that this situation was not as detrimental to the research as would initially appear. As the topic of this study was to determine where and why current methods of engaging scientists in dual-use discussions (and specifically educational initiatives) were falling short of their aims, having scientists reacting to the current means of introducing the topic of dual-use added further "fuel to the fire", so to speak, and significantly informed the discussions on the subject.

In all the fieldsites I struggled to pin down staff and students for interviews – something that recognised as a general challenge of sociological research<sup>71</sup>! I took considerable effort to promote my project both in the introductory seminar, the information sheet, and in my introductions to laboratory staff (as was initially conducted by my contact person). Nonetheless, in many cases it was often days between interviews, and many of them were subject to continual postponement. In response to my mentioning these issues, my contacts at the SA1 and KY1 site took it upon themselves to organize me an interview schedule with participants. Although this helped to get dedicated time from individuals, it did make me uncomfortable as I felt that the participants were not entirely voluntarily there. To counter this I emphasized the voluntary nature of the interviews repeatedly prior to the start of the official interview, as well as the obvious commitment to anonymity and confidentiality, and took pains to ensure that the information sheet had been properly understood. In all cases an informed consent form (appendix 3) was signed prior to any recording.

<sup>&</sup>lt;sup>71</sup> Indeed, the problems associated with setting up a research programme are regularly alluded to in most quantitative method textbooks, such as Bryman, 2008.

### 3.4 Implementing Methodologies

As discussed above, a number of different methodologies were used in order to answer the specific research questions. How exactly these were executed is detailed below.

#### 3.4.1 Focus Groups

In order to structure the discussion of the focus groups, it was decided that each session should take the format of a journal club. This had the advantage of being a structure that was easily understood by scientists, and had an existing place in each department timetable. Participants were issued with a copy of the paper under discussion, together with an information sheet and consent form (see appendices 2, 3 and 4) a maximum of a week, and no less than 48 hours prior to the session. Before the focus group commenced the consent forms were collected and the participants asked for any comments or questions regarding the process and content of the focus group. Interestingly, at no time throughout the fieldwork did a participant raise hesitations regarding the project or ethics, or refuse to participate or be recorded.

The paper selected for the journal club was published in Scientific American in 2009<sup>72</sup> by Taubenberger, Reid and Fanning. This paper described research done by Taubenberger's group on sequencing and recreating the Spanish flu virus. This research is often quoted as a classic example of a "dual-use dilemma" and is regularly used as a case study within the literature. Moreover, in many dual-use educational modules this case and other "dilemmas" are commonly used as a tool to demonstrate the dual-use potential of the life sciences. Thus, it seemed that were the participants to encounter dual-use as

<sup>&</sup>lt;sup>72</sup> Taubenberger, J. K.; Reid, A. H.; Fanning, T. G. (2007) <u>Capturing a Killer Flu Virus.</u> Scientific American, April 27

an educational module it would likely contain some reference to this or similar research projects.

Although the paper was published in a popular science magazine and did not contain original results, it was selected for two main reasons. Firstly, it described an entire research project and not an isolated aspect of the research. This allowed the research to be viewed in its entirety, and avoided excessive discussion on aspects of the methodology. Secondly, although it was a popular science article, it was written by the principle investigator of the research project, and therefore could be considered a relatively credible account of the research conducted. This is important due to the varying standards of scientific journalism in popular science and general media publications.

Discussion in the focus group was semi-structured, and participants were allowed to explore the topic and discuss with each other. Each focus group lasted at least one hour, which allowed sufficient time for ample discussion. The focus group was divided into three main themes, which are detailed below.

- 1. Initial reactions to the paper
  - a. Did the participants see value in the research being conducted? If so, what?
  - b. While reading the paper, were the participants alerted to any perceived risks and benefits of the research?
  - c. Did the participants feel that research such as this should be more strictly controlled than other types of research? What were their reactions to the delay in publication of the Spanish Flu sequence online?
- 2. The concept of dual-use
  - a. Based on a brief discussion on the concept of dual-use, did the participants feel that this research represented dual-use concerns?

- Leading on from that discussion, participants were asked their opinions regarding controlling dual-use - including pre-publication review of journal articles.
- c. Participants were then asked to discuss their perception of responsibility for dual-use control: scientists, governments, and the public with regards to dual-use issues.
- 3. Dual-use in the context of their experiences within the laboratory
  - a. Participants were then allowed to comment on their personal reactions to dual-use.
  - b. Did the participants feel that awareness raising and education for dual-use issues were useful initiatives?
  - c. How did participants discuss their personal impression of individual responsibility within scientific research and limits?

As mentioned above, the participation in the focus groups was entirely voluntary. Depending on volunteers' availability, focus group sizes varied according to interest (between 4 and 10 people), but no more than three focus groups were conducted in each fieldsite<sup>73</sup>. All focus groups were digitally recorded and transcribed at a later stage by the investigator with identifying features removed from data prior to its use in publications and presentations.

All in all, the focus group model worked very well. No doubt in part due to the familiar journal club format, at all four fieldsites the participants engaged well with the text and the discussion. Indeed, a number of participants thanked me after the focus group for what they perceived to be an interesting discussion.

#### 3.4.2 <u>Semi-Structured Interviews</u>

I had initially expected the primary focus of the fieldwork to be on the focus groups, with the interviews being conducted for further elaboration and

<sup>&</sup>lt;sup>73</sup> Note, the focus groups that I ran for the interest of the broader departments, based on requests from students and staff were not included in the analyses.

clarification of topics raised in the seminar and focus groups. However, very early on in the fieldwork I noticed that the subject matter raised during the interviews was significantly different from that gathered in the focus groups. Scientists were not necessarily more candid in their opinions on dual-use, however were more inclined to relate dual-use, harm, beneficence, responsibility and security to their own personal research. It appeared that on a "one on one" basis scientists spent more time discussing what dual-use meant to them and their work personally, rather than as a laboratory – in retrospect not a surprising distinction.

I thus decided to conduct as many semi-structured interviews as possible in each site, and allow interviewees to talk freely according to their interests and opinions while loosely sticking to the areas listed below. At each site interviewees included at least one PI, one laboratory technician, a representative from the ethics committee, a graduate student and a research scientist. Interviewees were issued with an information sheet and consent form (see appendices 2 and 3) at least 48 hours prior to the interview. Interviews were a minimum of 20 minutes and a maximum of 70 minutes depending on the availability of the interviewee. At the start of the interview the information sheet was briefly discussed and any questions arising from it addressed. The format for the interviews was quite loose, and interviewees were encouraged to progress between the topics for discussion (listed below) in their own time and in their own order. If a topic had not been covered at all, however, I made sure to introduce it into the conversation.

In most cases my previous scientific training and my understanding of the research being conducted at the fieldsites provided me with a good starting point for discussion. I introduced each interview as an attempt to better understand the different types of work that was being conducted in the laboratories, and then requested that after discussing the interviewee's research that I might be able to discuss mine in some detail. This approach worked very well and did appear to set the interviewees at ease. Thus, interviews were initiated by encouraging the interviewee to discuss their

research, and their experiences working in a specific context (laboratory, institutional, national). In particular, I encouraged the interviewees to identify what they perceived to be the strengths and weaknesses of their research environment.

I then followed on by providing a brief introduction to my work, and a small explanation (or recap if they had been at the seminars) of dual-use. Subsequent discussion was had on the interviewee's perceptions of dual-use, their opinions of the possibility of developing dual-use controls, and their opinions of the relevance of dual-use to their personal work, to their laboratory and on a national level.

Finally, the interviews were ended by a more general discussion on responsibility in research, and the interviewee's perceptions on pressing issues relating to responsibility within their own research environment.

These interviews were all entirely voluntary and depended on the participants' interest and availability. Each interview was preceded by a discussion on informed consent, confidentiality and anonymity. Furthermore, prior to commencing the interview I explained that I would be recording the interviews, and anonymising them prior to publication. Out of all the participants interviewed, only one declined to be recorded, although she was happy for me to take notes. By in large, however, all participants were comfortable with their opinions being recorded.

#### 3.4.3 Embedded Observations

As discussed earlier in this chapter, one of the primary foci of this research involved understanding the influence of the environment on the development of ethical principles within groups of scientists. Thus, an understanding of the laboratory – its strengths and weaknesses – was a valuable part of the data collection. As discussed above, and in contrast to more traditional sociology of

science research (such as that conducted by Bruno Latour and Sharon Traweek), I did not focus solely on the social interactions between the scientists, but rather utilised my previous experience as a scientific researcher to examine the physical and regulatory structure of the laboratories and the processes by which daily research was conducted.

Between 4 and 6 weeks were spent at each fieldsite to enable time for these laboratory and departmental observations. These were conducted at the discretion of the PI in charge of the lab, and with the (verbal) consent of those working in the lab. I did repeatedly check to ensure that all of those working in the laboratories understood my purpose and had been issues with an information sheet prior to my arrival.

These observations facilitated an understanding of the dynamics of the department and allowed similarities and differences between fieldsites. My background in laboratory sciences enabled me to shadow investigators in the laboratory to observe their routine functioning. This process allowed me time to not only view the physical and social structure of the laboratories, but also to establish relationships with the staff on a more informal basis than was possible with the interviews and focus groups.

A number of specific areas were identified for observation, and included:

- Number of staff working in the laboratory, their position on the career trajectory, and what types of duties and responsibilities they held in the laboratory.
- The types of experimental procedures being carried out, how they were carried out, and how the data was assimilated and analysed.
- The range of equipment available, what use was being made of the equipment, the maintenance of the equipment (and the difficulties associated there with), and how the equipment was acquired by the laboratories.

- The provision and use of common rooms/social areas, the social aspects of the laboratory environment, and the presence of a hierarchy within the laboratory.
- Division of duties in the lab (with regards to cleaning, waste disposal, safety, ordering and so forth), the interaction of these duties with external systems (such as waste disposal), as well as how the institutional, national and international requirements translated into daily duties.
- Laboratory organization, including laboratory meetings, journal clubs, supervision and mentoring meetings and daily informal teaching within the laboratory.
- Funding its provision and origin.

Furthermore, anecdotal information was recorded from the informal interactions with the scientists. All observations were recorded in a research journal, and any identifying features were removed from data prior to its use in publications and presentations.

## 3.5 Data Management and Analysis

All data – audio files, transcripts and field notes - were treated as strictly confidential at all times. Due to the limitations of internet capacity in Kenya and Uganda all files were stored on my password protected computer until they could be uploaded to the password protected data repository at the University of Exeter.

The focus group and interview audio files were transcribed and anonymised personally, although associated with metadata such as the date of collection, location, and level of career trajectory of the interviewee were associated with the anonymised files.

Each fieldsite was analysed separately according to thematic criteria that are detailed below, and which relate to the issues raised in sections 1.4 and 2.4. These themes formed the basis for the subsequent fieldwork chapters four to six.

Chapter four concentrates on examining the content of the ethical principles associated with dual-use. The main research question is whether the tightly bounded content of principles currently used in most discussions is at odds with the manner in which scientists in the sub-Saharan African sites interpreted the concept of dual-use. Furthermore, it investigates whether closely adhering to these tightly defined principles alienated, rather than encouraged, participant discussion. Interviews and focus groups were analysed for evidence of:

- Participants initial reactions to the dual-use concept when presented as the "possibility of well-intentioned research being misused for bioterrorism".
- The value that they attributed to this concern.
- Other possible harms arising from their research, and how they ranked the importance of these harms in relation to bioterrorism.
- How participants viewed the risks associated with their work in comparison to its benefits.

Chapter five examines the current emphasis on developing role responsibilities for scientists as dual-use controls. In particular it examines whether the reliance on a "web of prevention" model to discuss dual-use control adds value to dual-use discussions amongst scientists in sub-Saharan Africa. Interviews and focus groups were analysed for:

- Scientists' reaction to the idea of a "web of prevention".
- The viability of such a model in their environment (informed by the observation data).
- The effect of increasing regulation on their research and particularly on these regulations coming from foreign countries (informed by observation data).

- How scientists discussed how they would deal with dual-use events in their research. In particular how they discussed their responsibilities towards control.
- Whether participants tended towards a view of ethical controls as "bureaucratic exercises".
- Participants' view of their position in a collective endeavour to confront dual-use in the life sciences.

Chapter six looks at the problems associated with current models for fostering cultures of dual-use awareness. In particular it examines whether an overreliance on a "chain of mentorship" places African PIs under (perceived or real) considerable strain in the absence of postdocs and research scientists. This chapter was heavily influenced by the observational data gathered during the periods of embedded research. Interviews and focus groups were examined for:

- How scientists, in particular PIs, discuss the ethical and social aspects of their mentoring relationships?
- The feasibility of introducing dual-use awareness into the social culture of their laboratory?

This approach to data analysis allowed common themes to be identified between all the fieldsites, and for differences both between the African and UK as well as between the African sites to be recognized. Once identified, these differences were closely examined and the field journals and observatory data referred to in order to assess whether the causes for these differences could be ascertained.

The following three chapters discuss the fieldwork in considerable detail. In order to situate the fieldwork within the theoretical framework discussed in chapters one and two, however, each fieldwork analysis is preceded by a theoretical discussion that outlines some of the issues to be interrogated.

# 4. Engaging Scientists in Dual-Use Discussions: a <u>Problem of Content?</u>

It is obvious that any truly successful dual-use awareness-raising initiative requires more than just alerting scientists to the issues surrounding the concept. Instead, it must introduce the issues in a manner in which scientists identify with, see value in, and are willing to perpetuate. Thus, the identification of dual-use as a problem within life sciences research, and specifically as a consideration in one's own research, play key roles in facilitating discussion amongst scientists. Indeed, understanding how (if at all) scientists identify with the concept and its associated ethical issues is vital for initiatives that aim to "get scientists on board". Ultimately, such a better understanding will prove highly influential in fostering the ideal of a "common culture of awareness and a shared sense of responsibility within the global community of life scientists" (NSABB 2006: 5).

It is generally accepted, as discussed in chapter two, that within any model of awareness raising in scientific communities, educational initiatives play an important role. Activities which facilitate teaching scientists not only about the concept of dual-use, but also about their responsibilities have been endorsed by the BTWC and many other influential reports (such as NRC 2004, NSABB 2006). Thus, in recent years, a considerable amount of attention has been paid to how dual-use awareness should best be taught to scientists.

Currently, the majority of educational initiatives and attempts to build capacity within scientific communities have focused on *how* to teach dual-use to scientists, aiming to develop lessons that adequately take into account variations in teaching styles and requirements<sup>74</sup>. As well elaborated in the 2011 NRC book *Challenges and Opportunities for Education About Dual-Use Issues* 

<sup>&</sup>lt;sup>74</sup> This is well examined in NRC (2011). <u>Challenges and Opportunities for Education about</u> <u>Dual-Use Issues in the Life Sciences</u>. Washington D. C., The National Academies Press.

*in the Life Sciences,* a considerable amount of discussion has occurred on who is to teach scientists, how it should be taught, and what the expected outcomes of the undertaking are. It is of significance to note, as discussed in section 2.3.1, however, that discussions on *what* should be taught vary less than *how* one should teach them. Although it is generally recognised that "*no one size fits all*" (NRC 2011: 5) many of the courses share considerable common historical and ethical content and the presentation thereof (Mancini 2008).

Indeed, many of the courses, codes of conduct, and regulations rely on certain key principles to provide the ethical underpinning for their dual-use discussions, and promote the notion of a "global dual-use bioethics". Because of this tendency, it is not merely the regular identification of principles such as "beneficence" and "non-maleficence" that characterizes these initiatives, but also the assumption that these principles will mean the same thing to different communities of scientists.

In order to explicitly engage with this issue, this chapter uses the work of H. T. Engelhardt, particularly his 1986 book *The Foundations of Bioethics*. In this book Engelhardt rejects the possibility of a global, secular bioethics. Instead, he suggests that the current field of bioethics be examined in terms of the *content* of ethical principles, where contextually informed interpretations of principles are *content-full*, in comparison to the *content-poor* principles that comprise global ethical discourse. This distinction is examined in some detail within this chapter and contributes significantly towards the development of the chapter's themes.

The chapter then goes on to discuss the difficulties associated with suggesting the presence of a global secular ethics in dual-use education – namely presenting *content-poor* principles as *content-full* ones. In this manner I propose that the lack of critical engagement with the possible contextual variations in how different communities of scientists interpret these key principles may be a serious hurdle for dual-use education and educators. In particular, this chapter questions whether overlooking the possible contextual variations in ethical principles has the potential to alienate scientists (especially those from developing countries) from dual-use debates.

These questions are then reassessed from an empirical stance using some of the fieldwork data gathered in African and the UK. By conducting a comparative analysis of how the principles of "maleficence" and "beneficence" were discussed by African and UK scientists in connection with dual-use it is possible to better understand how and why the content of ethical principles should be positioned in the foreground of any discussions. Indeed, the fieldwork data strongly suggests that one of the barriers towards building dualuse awareness in developing countries is the manner in which key ethical principles are presented as *fait accompli* by most educational initiatives.

## 4.1 <u>Setting up the Argument: Critically Assessing Bioethics</u>

Chapter one discussed recent criticisms of the notion of a "global, secular bioethics". Alasdair MacIntyre and H. Tristram Engelhardt, amongst others, proposed some very compelling arguments regarding the impossibility of such a system without the guiding force of Christianity or some other independent source of morality. Thus, in the absence of a mediating external influence they suggested that modern secular bioethics has become irrevocably linked to contextuality – something which current systems of deontology and communitarianism are unable to adequately challenge. Nonetheless, despite such criticisms, a considerable amount of ethical discourse remains focused on the possibility of (or belief in) a global ethical system. Such approaches have, in the field of bioethics, become linked to principalism, and together tend to downplay the problems of a global bioethics.

Within chapter one, the problems of promoting a "global scientific ethics" was also discussed in relation to developments within life science ethics. I noted that, despite the problems of promoting such a global system, these issues were often (quite reasonably) underplayed in much life science ethics discourse. I suggested that this was largely due to certain key characteristics that I associate with research ethics.

Firstly, it must be highlighted that research ethics is predominantly focused on ethical conduct in research – and in particular avoiding research misconduct. This has led to the identification of certain "minimum standards" of behaviour (such as the "FFP" behaviours discussed in chapter one) that have been relatively globally endorsed by the scientific community (and the lay public). The identification of these "goals" for behaviour thus orients the use of ethical principles such as beneficence and non-maleficence as well as the content being ascribed to them within these discussions.

Secondly, research ethics tends to focus on behaviour within the laboratory, and is thus concerned with a specific range of activities. As how many of these activities, such as the use of human or animal subjects in research, are performed are governed by a high level of international agreement, it is likely that the different ethical communities will have similar approaches to these issues. Thus, it seems possible that the context in which research ethics is applied will not cause considerable variations in how these ethical discussions are perceived.

These two factors, I propose, have contributed towards the perception of a globally endorsed, secular research ethics underpinned by principalism. This perception, I propose, has been influential in the development of online research ethics courses and codes of conduct, as well as standard operating procedures, memoranda of understanding, and ethical review, all of which may be seen as successful in part due to the two characteristics mentioned above.

Therefore research ethics can be viewed in a number of different ways. It could be viewed as having successfully (to a certain degree) established a common secular morality to deal with life science research. Alternatively, however, it could be said that it *appears* to have established a global morality by virtue of the fact that the content ascribed to the ethical principles by ethical communities around the world are very similar due to its focus and area of implementation. Although the former interpretation is more popular, one must question whether the latter would contribute more towards the development of a nuanced understanding of bioethics in the life sciences – and assist with the problems associated with addressing broad social issues concerned with research.

In order to explicitly interrogate these hesitations, it is necessary to critically examine the issues relating to the principalist approach in ethics, for that is the approach which comes closest to the RCR model. In the following section principalism and its recognised limitations are briefly explored, after which an alternative view proposed by H. T. Engelhardt is introduced in some detail. Engelhardt's model will form the basis of this critique on the current manner in which ethical principals are dealt with in broad social issues such as dual-use.

#### 4.1.1 The Limits of Promoting a "Global Scientific Ethics"

As discussed in chapter one, a considerable amount of modern bioethics research – in particular that associated with principalism – has aimed to develop a secular morality that can reach across diverse communities of religious and ideological beliefs. While these ideals of a global secular morality are always tempered with a cursory nod to contextual variations in ethical cultures, the belief in global agreement on certain key principles<sup>75</sup> has been highly influential in the development of the field of bioethics. Indeed, the

<sup>&</sup>lt;sup>75</sup> These, as discussed in chapter one, include beneficence, non-maleficence, dignity and justice. These principles form the basis of principalism, and were first identified in Beauchamp, T. L., Childress, J. F. (2001). <u>Principles of Biomedical Ethics</u>. Oxford, Oxford University Press.

definition and widespread agreement on these key principles have formed the basis of the majority of modern bioethical debates.

Nonetheless, as discussed in chapter one, principalism and the idea of a communality of persons and a global secular bioethics have not been uncriticised. Critics regularly suggest that ideal of a universal ethics could cause many who work in applied ethics or bioethics to disregard the difficulties associated with such a system. In particular, as highlighted by H. T. Engelhardt in his 1986 book, *The Foundations of Bioethics*, such an approach may result in ethicists applying ethics as if it were obvious *which* secular ethics ought to be applied, thus imposing a particular moral vision, ideology or moral orthodoxy onto a situation (Engelhardt Jr 1986: p9).

This hesitation echoes those raised in the previous chapters regarding the broad social issues of science. As these issues reflect the social contract between science and society, and thus a specific contextual understanding of the issues at stake, might the presentation of ethical principles in these discussions as *given* rather than *continually negotiated*, have the propensity to stifle these discussions. Furthermore, if one attempts to extend a discussion beyond the national or cultural borders of a scientific community, might it be possible that too strong an emphasis on a global secular bioethics might alienate scientists from different backgrounds and appear "imperialistic"?

Thus, it would appear that more emphasis needs to be placed not on a communality that would unite persons, but rather the recognition of a diversity of human sympathies and sensibilities, and a plurality of visions regarding concrete moral obligations (Engelhardt Jr 1986: p41). Engelhardt suggests that society, instead of being viewed as a secular whole, be instead divided into what he termed "moral communities" which are united by common (and contextual) interpretations of the moral landscape. It is possible, in light of the problems associated with developing a global discourse on broad social issues in science, that the recognition of "moral communities" amongst scientists (in

contrast to a homogenous body of scientists) may be a helpful approach, as will be investigated in this chapter.

Therefore, instead of aiming for a global secular morality, Engelhardt proposed that in cases of moral controversy a minimum notion of ethics should be negotiated. This would serve as a fundamental requirement to ensure that the freedom of the members of diverse ethical communities is respected. This is particularly necessary if the authority of good arguments and common inspiration fails. In such cases the authority should be derived from the consent of those who fashion a community (and not, in the case of principalism, from some abstract list of principles). It is obvious to see how such an approach marks a considerable divergence from current methods of capacity building for broad social issues, but also presents a feasible alternative between ethical imperialism and relativism while respecting community integrity.

Furthermore, Engelhardt suggests that an extension of such consent would allow the establishment of public policy bodies or individuals which, in a particular setting, have the moral authority to impose moral points of view by force. Thus, unlike principalism, Engelhardt proposes a much more diverse interpretation of morality which is underpinned by continual negotiation both within and between ethical communities. It would appear that particularly in the case of broad social issues, this approach might be very helpful.

The concept of minimum consent provides an alternative form of moral discourse for secular ethics in comparison to traditional concrete ethical viewpoints. Engelhardt proposes that such a procedural ethics approach, based on the respect of the freedom of the moral agents involved, could be established even without the correctness of any particular moral sense (Engelhardt Jr 1985: p45). This makes mutual respect between individuals the foundations of secular bioethics – and thus, Engelhardt proposes, autonomy the lynchpin of creating these negotiated ethical systems.

Engelhardt's thesis gives life science ethics – and particularly the ethics of broad social issues – considerable pause for thought. Firstly, it (in my opinion, rightly) challenges the notion of a global secular morality that transcends any national or cultural boundaries. Can broad social issues concerning the life sciences be usefully interrogated from a global ethical stance, or would a more nuanced interpretation like Engelhardt's be more useful?

Secondly, Engelhardt's thesis also provides an outlet for a perpetual problem in bioethics, and one that is also present in life science discussions – what happens if two principles compete for primacy in an ethical discussion? Engelhardt proposes that a single principle, autonomy, should take precedent over all others to resolve such conflict. Thus, in such cases it is up to the moral community to determine how and what should take precedent – an action that cannot be generalized to other contexts<sup>76</sup>.

Although Engelhardt's challenging position has been heavily attacked over the years (Such as Beauchamp 1997), it remains an important alternative to strict principalism. Nonetheless, due to the large influence of principalism on modern bioethics, it is often considered a marginal consideration by many ethical discussions. It is my belief, however, that Engelhardt's system may provide valuable considerations for the ethics of the life science, and allow for the (perceived and required) differences between research ethics and the ethics of broad social issues to be highlighted and exploited to their benefit.

In conclusion, Engelhardt's position raises a challenging question: whether allowing the freedom and autonomy to each community to develop their own interpretations of morality possibly the most important means of developing bioethics? In particular, will such a refocus allow for a valuable contribution to ethical discussions, or plunge all arguments into relativism?

<sup>&</sup>lt;sup>76</sup> Indeed Beauchamp (amongst others) has questioned whether the right to be left alone is equitable to the obligation to receive permission (Beauchamp. 1997).

#### 4.1.2 <u>A Two-Tiered System of Principles</u>

In order to further expand on his idea of minimum consent, Engelhardt proposed a two-tiered system involving *content-poor* versions of ethical principles which have the ability to span numerous, divergent moral communities, and a *content-full* versions which refer to a particular community's interpretation of the principle in reference to their understanding of the "good life" (Engelhardt, 1985: 52). Importantly, content-poor bioethics is not able to provide any information regarding the "good life". It is rather a solution to the problem of common action by individuals drawn from diverse moral communities with competing views of the "good life" (Engelhardt Jr 1985: p52).

Using this system, raising an ethical question becomes an intellectual exercise regarding justification for actions. Interestingly, the principle of beneficence comes under scrutiny in that any specific ranking of goods depends on a particular moral sense and is therefore not able to reach across moral communities (Engelhardt Jr 1985: p75). Therefore, unlike the appeal to mutual respect through the principle of autonomy, the principle of beneficence requires specification within the terms of a particular moral community in order to be of any practical use, and thus the "good" which most moral systems require be done needs to be negotiated like all other principles.

By distinguishing levels of content, Engelhardt places *moral communities*<sup>77</sup> in a position of considerable importance, as it is within these communities that morality is provided with a particular socio-historical context informed by a fabric of customs (Engelhardt 2012). He suggests (in line with Hegel) that in order to

<sup>&</sup>lt;sup>77</sup> This is extended from the work of Hegel, who suggests that "in an *ethical* community it is easy to say what a man must do, what are the duties he has to fulfil in order to be virtuous: he has simply to follow the well-known and explicit rules of his own situation. Rectitude is the general character which may be demanded of him by law or custom … In an existing ethical order in which a complete system of ethical relations has been developed and actualized, virtue in the strict sense of the word is in place. Hegel, G. W. F. (1952). <u>Hegel's Philosophy of Right</u>. Oxford, Clarendon Press (Trans: T. M. Knox).

<sup>,</sup> Engelhardt, H. T. (2012). "Bioethics critically reconsidered: living after foundations." <u>Theroetical Medical Bioethics</u> **33**: 97 - 105.

offer more than empty moral platitudes one must enter into a particular moral community and embrace its particular viewpoint so as to possess a concrete understanding of the right and the good. Only within such a particular sociohistorically conditioned context can morality gain content (Engelhardt, 2012: 98).

Engelhardt's work thus attempts to address plurality in ethics without lapsing into relativism. Despite critiques from principalist ethicists (such as Beauchamp 1997), Engelhardt's system provides a much needed focus on the issues relating to contextuality within ethical discussions. Furthermore, by using his proposal of a two-tiered system of ethics, many of the seemingly intractable ethical conundrums may be resolved through the intellectual analysis of the content and priorities held by differing ethical communities.

Notwithstanding the value that Engelhardt's approach might contribute towards ethics in the life sciences, it has yet to make a significant impact on the current approaches. As discussed above, considerable effort has been made in research ethics to establish a commonality of purpose amongst diverse groups of scientists – to a marked degree of success. Furthermore, the emergence of codes of conduct could be taken as an indication of a communal morality. However, as the following sections ask, is this truly the case, or are we missing the wood for the trees?

#### 4.1.3 Straining at the Confines: Ethical Principles and Broad Social Debates

In chapter one some of the characteristics relating to integrating broad social issues into life science ethics education were discussed in some detail. One of the particular considerations was that these issues arise based on the global responsibility of scientists towards improving the state of humanity, and the social contract that exists between science and society. As these contracts, it would seem reasonable to suspect, vary around the world, it seems likely that

the notion of moral communities may prove a valuable means of understanding these variations.

If one allows international scientific community to be divided into moral communities, it becomes increasingly difficult to visualise a "global secular ethics" that would be equally applicable in all these communities. Rather, it would seem that Engelhardt's notion of a "minimum consent" regarding the importance of certain ethical principles is all that could be aspired to. Similarly, it is feasible to assume that within the different more communities, these "content poor" principles transition into "content full" ones depending on the community's particular interpretation of the principle in relation to their understanding of the "good life", *vis-á-vis* (at least in part) their goals for the scientific research.

Thus, in considering these broad social issues it becomes important to consider exactly how and why content is ascribed to the principles underpinning these discussions. In particular this would be of significance when attempting to transport discussions across the boundaries of ethical communities, or to involve more than one ethical community in discussions. Furthermore, as it is evident that broad social issues elicit regulation and legislations, one must consider how far one can expect such behaviour guidance to be applicable beyond a single ethical community.

As Engelhardt suggests, if one embraces the concept of moral communities and content-full interpretations of ethical principles, the autonomy of communities to determine the content becomes the paramount consideration of any international discussion – something that seems considerably at odds with the RCR emphasis on a global secular bioethics.

## 4.2 <u>The Dual-Use Debate: Are Context-Dependent Variations</u> <u>Important?</u>

The problems associated with the ideal of a "global secular bioethics" may be particularly pertinent to the dual-use debate, and particularly one of its fundamental goals of creating a "common culture of awareness and a shared sense of responsibility within the global community of life scientists" (NSABB 2006: 5). Interestingly this idea of creating a global response to dual-use is often accompanied by the recognition that dual-use responses cannot be limited by national borders, and requires coordinated action on a regional and global level (Such as NRC 2004). However, despite the obvious importance of this goal, it is important to question whether a global ethical response for dual-use is possible, or if not what alternatives should be considered.

As discussed in chapter two, dual-use ethics is still an emerging field and has only recently received dedicated attention. This rather sporadic coverage, together with the undeniable association of this debate with the RCR model, has largely resulted in a vision of a "global, secular, dual-use bioethics" being promoted. Perhaps unsurprisingly, the issues relating to global ethics discussed above have as yet received little attention. A critical examination of the developing trends in dual-use education and awareness-raising, such as the emergence of codes of conduct, funding requirements and online educational modules, all suggest that the idea of "content variation in principles" between different communities of scientists are rarely addressed.

It is my position that this promotion of a "secular global" bioethical approach - as a legacy from RCR and medical bioethics - may foster confusion within scientific communities instead of promoting harmonization. Although appealing to a global bioethics is a useful rhetoric tool for an emerging issue such as dual-use, I believe that it will ultimately serve as a stumbling block for the eventual integration of non-Western countries into the dual-use debate, as will be discussed in the fieldwork below. Chapter two discussed the evolution of the concept of dual-use in some detail. In particular, it was highlighted how dual-use has gradually evolved from its beginnings in the nuclear sciences, to come to refer to a number of interrelated concepts (Atlas 2006). Nonetheless, all of the formulations of the concept are united by the central ideas of *beneficial* scientific research being used to cause *harm* (Miller 2007). In contrast to biosecurity discussions, dual-use is further identified as the misuse of *scientific information* rather than reagents, samples or equipment. Furthermore, as elucidated in chapter two, due to the nature of dual-use as a possible future event involving a third party bent on malicious purposes, distributing responsibility for dual-use issues is no easy task.

Even such a brief analysis highlights the importance of certain ethical principles to any version of the dual-use concept. In particular, the principles of beneficence, and the interrelated principles of harm and maleficence are vital to any dual-use discussions. Therefore, if one indeed abandons the notion of a global understanding of these principles that transcends borders, this observation thus raises questions about how (and why) content would be ascribed to these principles by different moral communities. Furthermore, it would be important to query whether different interpretations of these principles affected how the concept of dual-use, and thus the responsibility for it, were interpreted in different moral communities.

It would thus appear that discussions on the content of these principles should be of considerable importance in raising global dual-use awareness. However, as is evident from chapter two, this is rarely the case in dual-use awareness raising and education in the life sciences. Indeed, most initiatives the key within the dual-use debate present ethical principles as possessing pre-defined content, and the possible variations of this content are rarely explicitly mentioned. Thus, the principles of harm and maleficence within dual-use debates predominantly refer to the intentional misuse of information by substate actors for bioterrorist actions. Beneficence, on the other hand, is taken to refer largely to well-regulated research conducted in an academic environment. In this way (and largely due to the influence of the RCR model), the ethical principles underpinning the dual-use debate are rarely closely examined in a contextual manner – a state of affairs that gives out the misimpression of a preestablished global ethics governing the issue.

If one does abandon the impression of a global ethics for dual-use and instead examines the contextual variations possible in the field, it becomes apparent that the content currently being promoted evidently originates from a developed, Western community and clearly reflects both the context and concerns of this community. Its dominance in dual-use discussions is by no means surprising, due to the strong presence of these countries (such as the UK, USA, Australia and the EU) in these debates and their considerable efforts towards awareness raising in the global life science community. Thus, while the prominence of these certain versions of the dual-use debate is understandable, it is also important that one questions why other interpretations of the debate (based on varying content attributed to ethical principles) from other moral communities do not also feature in these discussions.

Furthermore, if one does indeed recognise the possible variations in the content of ethical principles in the moral communities that comprise the global scientific community, it also becomes important to examine two interrelated issues. Firstly, if the debate makes use of specific *content-full* versions of ethical principles – thus binding the concept of dual-use to its Western interpretation – it is possible that it may in fact alienate other ethical communities trying to access the debate. Secondly, the growing support for codes of conduct and online learning present *content-poor* versions of the ethical principles underpinning the dual-use debate without any reference to how the interpretations of these principles may vary according to context and community. Thus, many initiatives are undermined by the assumption that the content that is ascribed to these principles will be the same between ethical communities.
These issues are, of course, based on the theoretical speculation from the preceding chapters, and it was thus important that they be tested against practical evidence from practicing scientists. Thus, the next section highlights not only how these investigations were carried out, and how the data were analysed.

# 4.3 Using Fieldwork to Inform the Discussion

This section of investigation, in particular, benefited from the comparative nature of the fieldwork. In particular, the fieldwork allowed me to test the limits of the hypothesis outlined above – one which I acknowledge to be rather unusual. The belief in this hypothesis and the value of conducting empirical research stemmed from my own experiences as a scientist in both South Africa and the UK, and my perceptions of different moral communities within the global life science community. In a large part, the differences that I perceived were due to differing social priorities which obviously led to differing hierarchies of harms and benefits. Using this experience as a background for this research, I set about understanding examining issues which came to the forefront during discussions on dual-use, and attempting to understand how these explicitly named issues would alter the content that the participants ascribed to the key ethical principles under discussion: beneficence, non-maleficence and of course the concept of harm.

#### 4.3.1 Potential Considerations in an African Context

When considering what content moral communities of scientists would ascribe to the concepts of "maleficence" and "beneficence" it is obviously of considerable importance to consider the social environment in which the research is taking place. Within the African context, one of the primary health (and therefore health research) considerations remains the HIV/AIDS pandemic. The three African countries I visited all had extremely high levels of HIV infection and complicated histories of treatment roll-out and social awareness. This was particularly true of South Africa, which had a turbulent history of antiretroviral therapy (ARV) roll-out due to a period of "HIV denialism" by the Mbeki regime<sup>78</sup>.

Largely due to the high infection rate in sub-Saharan Africa, many countries have hosted clinical trials for a number of related HIV treatments, including vaccines, ARVs, and transmission retardants. However, the majority of these trials are sponsored and largely conducted by foreign research consortia, and are not in the direct control of African scientists. This situation is no doubt exacerbated by the fact that despite African governments placing a high premium on the potential for scientific developments to alleviate or eliminate the HIV problem, few (apart from South Africa) invested significant amounts of money into HIV research<sup>79</sup>. Indeed, as mentioned in chapter three, this lack of funding is indicative of the broader spectrum of problems associated with R&D in Africa. Even with the recent prioritization of scientific research by the African Union (AU), few African governments invest even 1% of the Gross Domestic Product (GDP) into scientific research (COHRED 2010).

Despite the health burdens of these countries, in many cases the available research money is directed towards agricultural outputs and food security. In addition to the impact that this has on health research, the emphasis on agricultural research has also had a significant influence on biosafety and biosecurity discourse in the region. To date, most of the capacity building initiatives centre on genetically modified organisms, in contrast to the increasing emphasis on the threat of deliberately caused bioterrorism and warfare which is emerging in Western countries (UNAS 2008: 4). Despite recent attempts to raise the profile of biological warfare and dual-use issues within African

<sup>&</sup>lt;sup>78</sup> This is well-documented, but for a brief overview see

http://en.wikipedia.org/wiki/HIV/AIDS\_denialism (accessed 23/10/2012). <sup>79</sup> For a comprehensive overview, see

http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC22 86 Sourcing-African-Solutions en.pdf (accessed 20/12/2012).

science<sup>80</sup>, and the majority of African countries being signatories to the BTWC, such issues remain largely in the background of African scientific discourse and government involvement in science.

In relation to scientific discourse, it must also be emphasized that the majority of African countries have a low level of science literacy within the general population. Indeed, in most countries secondary and tertiary education are not accessible to all learners<sup>81</sup>, which has a large impact on general scientific discourse. Furthermore, this low level of literacy is often reflected in the popular science journalism and information to which the public has access<sup>82</sup>.

While familiarizing myself with the specific social context of each of the fieldsites, the issues discussed above appeared to me to have the potential to significantly influence the content of the ethical principles within the dual-use debate. Careful attention was paid, while conducting the methodologies and while coding the results, to how these issues appeared in relation to the concept of dual-use.

# 4.3.2 Data Gathering and Analysis Synopsis

In chapter three, section 3.3.2 detailed issues relating to getting endorsement from the scientific communities at the various fieldsites. This section highlighted not only the low level of dual-use awareness<sup>83</sup> amongst the scientists at all the fieldsites, but also that many of the participants did not understand the purpose

<sup>&</sup>lt;sup>80</sup> I refer here to the Kampala Compact (2005) and the subsequent Nairobi Announcement (2007).

<sup>&</sup>lt;sup>31</sup> For a comprehensive overview, see

http://siteresources.worldbank.org/EDUCATION/Resources/278200-1099079877269/547664-1099079967208/Developing\_post-primary\_edu\_africa.pdf (accessed 19/12/2012).

<sup>&</sup>lt;sup>82</sup> This statement is based on my own opinion, which has been formed by the regular surveillance of sites such as <u>http://allafrica.com/science/</u> that compiles scientific news articles from news agencies on in the sub-Saharan African region. Furthermore, such opinions were also reiterated by many of the scientists that I talked to during my fieldwork.

<sup>&</sup>lt;sup>83</sup> Most of the participants (even in the UK) had never heard of the term "dual-use" before, and were often unfamiliar with the contrast between the misuse of materials versus the misuse of information.

of my research at their institutions. To this end, I decided to not only issue information sheets to all participants, but also to conduct an introductory seminar during the initial phases of my research at each site. Although this did, to some level, pre-alert the participants to the issues that I wanted to discuss, it nonetheless proved a useful element in the overall project.

The purpose of the fieldwork was to examine how current educational and awareness-raising initiatives potentially did not reach their desired impact level due to the idiosyncrasies in the way in which dual-use bioethics was portrayed in them. Thus, by presenting dual-use to the participants according to the conventional "Western" model<sup>84</sup>, I was able to provide them with a platform from which to agree or disagree. This approach proved extremely successful, as many of the participants reacted strongly to the manner in which the concept was presented, and the subsequent conversations involved them clearly detailing what they supported or rejected about the concept.

As also discussed in chapter three, I followed up this introductory seminar with individual interviews, and that I initiated these interviews by inviting the participant to briefly discuss their work and aspirations. This served a double purpose, firstly encouraging the participants to talk about their own work visibly set them at ease and provided a good foothold for further discussions. Secondly, as I had a science background (and in particular experience working both in the UK and in South Africa), and was able to contribute to these discussions, I found it to be a simple and effective means of establishing a relationship with the interviewee. It is my opinion that it was particularly because I was perceived as "one of them" that the interviewees opened up to me. Had I been solely a social scientist (particularly a non-African one) it is my opinion that the interviews at the African fieldsites would have progressed differently.

<sup>&</sup>lt;sup>84</sup> Briefly, as the potential for beneficial scientific research to be intentionally misused by a third party (a sub-state actor) for nefarious purposes (bioterrorism) (Miller, 2007).

Allowing the time to establish a relationship with the interviewees, and encouraging them to talk about their work created a space in which scientist felt comfortable to linking their further responses to their personal opinions and experiences. In doing so (and in contrast to the difficulties experienced during the first interviews that utilized a more rigid question/answer format), the interviewees were able to critically engage with the concept. This approach thus avoided the possibility of more formulaic answers.

Similarly, at the beginning of each focus group I introduced myself and provided the participants with a short biography and synopsis of my research. I took time to elaborate on my previous scientific career which, I felt, established my position as a "scientist" as well as a "social scientist". Although the main purpose of the focus groups were to discuss the paper which had been issued to the participants, in every focus group there was a considerable amount of discussion regarding the scientific validity of the research, which was often related to the research being done within the specific laboratory context. I found that these discussions of the scientific aspects of the paper often provided a useful interlude by which to reorient the group and introduce further topics.

When I came to analyse the transcripts for this section I specifically looked for themes that related to the participants' understanding of the concept of dualuse, and the principles of beneficence, non-maleficence and harm. By thematically analysing them in this way I was able to isolate certain issues relating to the content of ethical principles that are discussed below. Similar thematic analyses had previously been used in related studies on dual-use (Rappert 2007). In a related manner to these previous studies, this chapter does not attempt to summarize "what happened" by providing statistics of how many times specific responses were made. Rather, the broad themes of commonality will be utilized as generalizations on which further ethical discussion may be grounded - an approach that has previously been recognised to be well suited to semi-structured interviews and focus groups (Bryman, 2008). Interestingly, the responses of the African scientists appeared very similar between the fieldsites, which (as discussed later) gave rise to some interesting speculation of how to understand moral communities in science. Due to this observation, in this chapter the responses from the four African sites were grouped together and compared against those arising from the UK site. In itself, the similarities of the responses obtained (in this regard) from the four African sites surprised me. However, when reconsidering this in retrospect, I recognised that many of the participants at these sites explicitly referred to "Africa's problems" when discussing these issues, which would lead to the possible conclusion that (at least in this case) they were identifying themselves as a moral community, and thus present some unity of ethical content between the sites<sup>85</sup>. In the following sections the analyses of the content of the different ethical concepts are discussed in some detail, specifically contrasting the content ascribed by the UK scientists to that identified by the African scientists.

# 4.4 Examining the Concept of "Harm"

Dual-use discussions trade heavily on the concept of harm as a motivator for concern and action. How the idea of harm – the result of "malicious reuse" - is understood is therefore becomes vital for ensuring that scientists engage in the concept. As discussed in chapter two, over the last century the dual-use debate has become strongly associated issues relating to biological weaponry. For this concern, as is evident from the number of signatories of the BTWC<sup>86</sup>, there is broad global support. Furthermore, this commitment towards minimising the possibilities for the development of biological weaponry has

 <sup>&</sup>lt;sup>85</sup> This approach stands in contrast with the observations from the subsequent two chapters, which investigate implementing dual-use awareness on a local level, and perpetuating a culture of responsibility and awareness respectively.
<sup>86</sup> The BTWC emphases the prohibition of acquisition and use of biological and toxic weapons

<sup>&</sup>lt;sup>86</sup> The BTWC emphases the prohibition of acquisition and use of biological and toxic weapons under any circumstances, and the creation of an environment in which no country dares to argue that biological weapons can ever have a legitimate role in national defense Kahn, M. (2006). Preparations and expectations. Presentation to the United Nations General Assembly First Committee. <u>Sixth Review Conference of the Biological and Toxin Weapons Convention</u>. New York.

resulted in widespread agreement of policy and governmental levels. Subsequently, there have been rising concerns over bioterrorist attacks and the development of biological weapons by sub-state actors. This link between harm and bioterrorism has unquestionably been influenced by recent terrorist attacks around the world, which have collectively contributed towards a heightened perceived threat from international terrorism (Kuhlau 2008)<sup>87</sup>. Interestingly, while the motivations for these sub-state aggressors are understood vary and include religious, political or, ideological; the results of their actions are similar: to deliberately target or disregard the safety of non-combatant civilians.

Nonetheless, it must be noted that biological weaponry and terrorist activities are only one set of the possible harms that could be envisioned in the dual-use discussion. As will be discussed below, a number of different permutations on the idea of "misuse" and "harm" are possible without undermining the integrity of dual-use as a concept. Nevertheless, these variations are rarely alluded to in educational initiatives, and the concept of "harm" is usually presented as solely referring to bioterrorist activities and a threat to national (and international) security. Based on the discussion above, it is therefore important to question whether such as close relationship between the concept and content is sufficient, or even feasible, for dual-use education on a global level.

Interestingly, the close relationship between the concept of "harm" and this specific content within dual-use debates has already proven problematic in the UK and USA. A recent survey suggested that many scientists doubted the likelihood of such harm ever arising from *their* research (AAAS 2009), and in so doing thus questioned the applicability of dual-use as an issue for their *personal* responsibility. Nonetheless, it must also be noted, that while in many cases these scientists struggled with it as a personal concern, the broader possibility

<sup>&</sup>lt;sup>87</sup> The debate on the generation of dual-use research by the military, and the need to conduct such research as a means of "staying ahead" of terrorist activities is another broad topic that will not be discussed in this thesis. It is examined in Rappert, B. (2010). Education as ... <u>Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Warfare</u>. B. Rappert. Canberra, Australia, Australian National University Press.

of harm arising from terrorist activities was less questioned – probably due to the recent terror attacks in these countries.

The continued focus on "experiments of concern" also presents a complicating factor within life science dual-use debates, as it emphasizes an almost causal link between the research of concern and the harm arising from it. Despite the recent calls by the Lemon-Relman report (NSABB 2006) and various academics (Including McLeish 2007) to broaden the threat spectrum, little has been done to alter the implicit assumption of dual-use as a potential somehow embedded within the beneficial research.

Taken together, these observations present a specific interpretation of the concept of harm that focuses heavily on the possibility of bioterrorism and bioweaponry being the nefarious result of the misuse of information. This interpretation of harm arising from dual-use events, of course, clearly reflects the concerns of Western nations which have not only a high level of scientific research but also have recently been the target of recent terrorism attacks. However, it must be questioned whether this interpretation is the only one that will guide scientists to the central aspect of dual-use: the idea that research is being misapplied to intentionally hurt the general public.

Liberated from the strict focus on bioterrorism it is possible that this idea could be linked to other interpretations of misuse and misapplication. As suggested by Brian Rappert, "weapons of mass disruption", instead of "weapons of mass destruction" may be an alternative means of visualising the products of dual-use events (Rappert 2010: 13). From this it may be suggested that the utilisation of biological information to spread fear or panic may be as effective a weapon as one that inflicts mass casualties.

If such speculation is extended further, and dual-use is liberated from the expectation that misuse of research will result in biological weaponry, it

becomes possible that other forms of fear mongering and panic-spreading may be included in the dual-use debate. Such alternative interpretations of the concept of "harm" within dual-use may serve as valuable tools for building capacity in countries in which bioterrorism has not the same position of importance as it does in certain Western countries.

This section therefore questions whether the strict association between dualuse and bioterrorism (as the misuse of research for malicious purposes) serves as a potential barrier to the uptake of the concept by scientists. In the following sections the fieldwork responses concerning harm are discussed in some detail.

#### 4.4.1 The UK: We're More Concerned About Biosecurity ...

During the fieldwork conducted in the UK I noticed that participants in the interviews and focus groups made a rapid transition from the introduced concept of dual-use to issues relating to more traditional biosecurity topics, such as theft and/or misuse of samples. Indeed, within one focus group I struggled to maintain the focus of the discussion on dual-use, and not biosecurity misuse of physical samples and reagents. I had to reiterate the difference between misuse of samples and information three separate times in order to reposition dual-use within the biosecurity debate. Thus, it would appear that the participants did in fact place dual-use issues at the end of the biorisk spectrum, as is the case in many current dual-use discussions (such as IoM 2002).

Within these discussions on bioterrorism, it became rapidly apparent that the participants distinguished between the *threat* of bioterrorism and its *likelihood*. While recognizing that the information and materials generated by modern scientific research provided ample opportunities for misuse, scientists pointed to the difficulty of doing so in a non-laboratory environment. The HoD of the department succinctly summarized this concern, saying: "... there's plenty of information out there that someone could gain today and take a viral construct

and manipulate it to make it into a bioterrorist weapon – there's more than enough information out there anyway. But they would have to have an appropriate place to do that, so that restricts it in some sense" (UK1-8: HoD).

These hesitations were repeated by a number of different participants. Thus, biosecurity issues tended to be interrogated mainly through discussions of current biosecurity regulations in place to limit access to samples, reagents, and materials as well as access to institutions and staff surveillance. These debates highlighted that the participants were not as worried by the possibility of misuse of information, but the threat of biosecurity. This, in turn, was lessened by a belief in the fitness and effectiveness of the regulations currently in place to control it.

In the focus group, as well as in some of the interviews, the link was made between the difficulty of conducting illicit research outside of a laboratory environment and the threat of the "terrorist within". Two participants conducting a joint interview had this exchange:

# 12: "... Because what is a bioterrorist?

13: it's probably somebody like you and me who's had a very bad day and a very bad life who's had the same training.

LB: you mean the "terrorist within" scenario?

*13: yeah, if anything that's where it would be. You say it's very easy to get this training. I've been working for a number of years to get these skills.* 

12: yeah, it's not that easy, but on the other hand, how many nuclear threats can we have? How many bioterrorist threats can we have, and how many of them come from these blacklist of countries that are a threat to the global community and how many are coming from legal governments, and what kind of funds are going to these places. You don't know what the governments are doing, and this could be called bioterrorism." (UK1-2 and UK1-3: postdocs).

Such discussions on the misuse of science from practicing scientists were followed by comments on related issues, such as the 2006 call by Al Qaeda's for biological scientists to join their movement<sup>88</sup>. From these discussions it became apparent that the participants identified the most immediate threat (aside from biosafety incidents) as coming from within the scientific community or from governmental programmes particularly dealing with biological weaponry.

Reviewing the transcripts therefore suggested that a considerable amount of discussion in the UK focus groups and interviews centred on biosecurity issues and the threat of misappropriation of scientific research products. Many of the participants were highly knowledgeable about recent biosecurity and bioterrorist attempts, such as the 2001 Anthrax attacks in the USA and the Aum Shinrikyo activities in Japan. When one considers the high level of exposure that these scientists have to international political affairs, when taken together with the bioterror-adverse culture of the UK, which has recently been subject to attempted and successful terror attacks<sup>89</sup>, it is perhaps unsurprising that the threat of terrorism arising from scientific research was not highly questioned.

Nonetheless, it became apparent that – aside from malicious release of something like viral stocks – the participants believed that the facilities and expertise needed to manipulate modern research were considerably beyond most terrorist organisations. Instead, they placed most of the threat within the science community – the "terrorist within" scenario similar to that which precipitated the Anthrax attacks.

From this fieldwork, it would therefore appear that within the UK context the scientists were able to freely access the concept of dual-use - particularly as an

<sup>&</sup>lt;sup>88</sup> <u>http://www.jihadwatch.org/2006/09/al-qaeda-in-iraq-leader-calls-scientists-to-jihad.html</u> (accessed 19/12/2012).

<sup>&</sup>lt;sup>89</sup> These include recent attacks such as the Glasgow Airport attack on 30/06/2007 and the London Underground bombings on 07/07/2011.

extension of the biorisk spectrum. Thus, the commonly employed definition of harm that accompanied my presentation of the dual-use concept was accepted as a legitimate concern. Interestingly, however, it would appear that the principle of maleficence as it is at work in the dual-use concept met with less straight-forward acceptance, as many participants were concerned with the *likelihood* of such terrorist attacks. Without experience in the USA, however, it would be impossible to determine whether this differed between the two countries and thus was a significant alteration in content attribution between the two.

4.4.2 <u>Africa Replies: It's an Interesting Hypothetical Problem ...</u>

As I mentioned above, the participants' responses to the idea of harm as a result of dual-use didn't appear to differ greatly between the African sites. To some degree this surprised me, as I had suspected that South Africa's earlier biological and nuclear weapons programmes (Venter 2012) would have contributed towards a greater acceptance of the threat of biological warfare or the possibility of bioterrorism amongst the scientific population. However this did not appear to play a major role in how South African scientists accessed the dual-use concept, and indeed there were very few references to the Apartheid government's weaponry programmes during the fieldwork.

Although I had no problems getting scientists to talk about dual-use issues, it became rapidly apparent that the African interviewees' responses differed markedly from those collected in the UK. One of the most prevalent opinions was that dual-use was an interesting, yet hypothetical, problem. Statements such as: "So sure, we're ... willing to discuss because it's more academic, a philosophical interest. It's really not pertinent to us" (SA1-12: PI), were common in all African sites and appeared to be distributed evenly along the career trajectory.

It appeared that many participants thus initially distanced themselves from the concept of dual-use by viewing it purely as an academic problem. It was interesting to note that despite clearly indicating that dual-use was not a problem in their daily research, participants nonetheless appeared to relish the opportunity to discuss the topic. This suggested that there was not a problem engaging the participants in ethical discussion, which might have been initially suspected, but rather an issue with the content of the principles I was employing to illustrate the argument.

Another commonly expressed sentiment was that the dual-use was an issue for the West. Many of the participants were quick to point out to me that dual-use was not (and should not) be a concern for African research. As one PI succinctly put it to me: *"[w]hen we came to the bioterrorism thing<sup>90</sup> that you mentioned then I thought it was totally irrelevant and paranoid on the part of the Western world"* (SA1-8: PI). This idea of "their problem" versus "our problems" came across strongly in all four African fieldsites, and many interviewees made references to the difficulties that they experienced in their research as a "justification" for not considering dual-use issues.

As one student in Kenya mentioned, "... the people in the States and the UK should worry about that because they're more advanced. Here in Africa we don't have the equipment or reagents, so we don't have the time to do that. We're fighting for how to do our research. We don't have time to be getting biological weapons" (KY1-5: MSc student). I noticed that particularly in the Kenyan and Ugandan sites, where there is less support for scientific research from the government, there was definitely a feeling of needing to build up African scientific research before worrying about issues such as dual-use. As one Kenyan technician put it: "I think for Africa at the moment it's not a problem. We're trying to build up ourselves, and that is by publishing and marketing ourselves" (KY1-4: technician).

<sup>&</sup>lt;sup>90</sup> The participant was referring to the definition of dual-use that was provided on the information sheet, that beneficial scientific research had the potential to be misused for malicious purposes, such as bioterrorism, by a third party.

Interestingly, when reviewing the transcripts I noticed that many of the respondents have appeared confused when I asked them about dual-use in relation to their research. One PhD student at the SA2 responded to the explanation of dual-use by saying: *"I haven't grown up with the concept of American, British and European sciences, so I'm not sure what all the paranoia is about"* (SA2-3: PhD student). Similarly, another student at the SA1 site stated their opinion that *"... in Africa we just don't deal with such questions. I think it's more in the domain of the western world – America, UK – where the threat of bioterrorism is a very real threat, and so I think this issue is poignant there" (SA1-3: PhD student). Similar responses were also had from scientists higher up on the career ladder, such as Pls, which seemed to suggest that many of the African participants were actively positioning themselves as separate from Western scientists. As these responses came from all points on the career ladder, it was unlikely that such distinctions could be simply interpreted as due to the funding and research difficulties mentioned above.* 

That said, however, it was obvious that most participants at least partially linked the lack of facilities, funds, or advanced research projects in Africa to their understanding of dual-use as a Western issue. Particularly the PIs and permanent researchers expressed their opinion of dual-use as a Western problem with frustration. Often, this frustration was linked to the assumption that dual-use controls would further complicate their working environment, through increased restrictions or requirements.

However, in three cases PIs made the link between their shortage of funding and the amounts of money spent on dual-use awareness and control. One PI at SA1 explicitly stated this, contrasting the funding for dual-use to the perceived need for additional funding for HIV research. She said: *"it's just huge amounts of money that go into fighting this phantom threat where I feel like we have more important things to do here as we're in the middle of a huge HIV and TB epidemic and we just want to get on with doing the research. It was not an*  issue that I'd ever considered before, and quite frankly I don't feel it's very relevant" (SA1-8: PI).

The frustration at the perceived amount of money diverted to dual-use control was also linked to shortages of funding within African science and poor infrastructure. Many participants expressed opinions that science in Africa would benefit more from investments in research and infrastructure than (what they saw as) improving biosecurity regulations on the continent.

These excerpts (I hope) clearly demonstrate the some of the problems that the African scientists had with accessing the concept of dual-use. It is noteworthy that, although many of them explicitly stated their understanding of the concept by referring to it as an *"interesting problem"*, they nonetheless did not engage with the content of harm or malicious misuse as they are usually presented in dual-use discussions.

## 4.4.3 <u>A Version of "Harm" That Everyone Can Access?</u>

In dual-use debates, the content-poor version of the principle of harm involves the idea of information passing out of the control of the scientist and being misused in some way. However, as was evident from the fieldwork, African scientists struggled to attach value to the content that was subsequently attributed to the principle of harm: that of bioterrorism and bioweaponry. However, during the fieldwork I regularly noticed that many of the participants both in the UK and in the African sites proposed alternative interpretations of harm arising from information misuse.

When I analysed all the data together it appeared that there was one particular alternative interpretation that resonated in a context-specific manner with scientists across ethical communities: that of fear-mongering in the press. It appeared that this issue was something which not only was attributed value by all participants regardless of the fieldsite, but also that it embodied the key issues relating to the content-poor version of harm used in most dual-use discussions.

In the UK, it was very interesting to note that many of the interviewees prioritized communicating of research as a fundamental responsibility of scientists for dual-use control. Thus, the discussions on misuse of information were rapidly equated to the manipulation and misreporting of information. In such discussions the possibility of harm was recognized to be immediate and serious. One scientist, for instance, saying: *"[d]ual-use in the sense of manipulation of information, yes it can have a negative impact"* (UK1-4: researcher).

In these discussions it became rapidly apparent that the misuse of information was often linked to the misinformation of the public. Indeed, as one researcher stated: *"I don't know if it's really dual-use, but the public has a lot of misconceptions, and they have a lot of myth and false ideas"* (UK1-4: researcher). This was further explored in many other discussions, such as the one below:

"12: One important point is that once the information crosses the barrier from the science community into the public you can create a lot of panic through misinformation. The media is not very good at giving the right information. That's another point of misuse. The scientists need to engage and give the media proper information so the less issues you are going to have and the public is go for the science and that's why they should be part of these committees [to control dual-use]. Scientists, but also lay people.

13: If scientists can't communicate the importance of our research to a layperson when we're not doing it right. We shouldn't be doing research if we can't communicate it. *I2: ...* So making sure that scientists are well covered in the press is important." (UK1-2 and UK1-3: postdoc).

When questioned on the harm arising from misinforming the public about scientific research, three of the interviewees used specific stories to illustrate their points. One told a story about the HIV vaccine and a poorly reported claim of curing HIV/AIDS. She said: "[t]here was this clinical trial that happened for a potential HIV vaccine that was developed by, conducted by a Spanish group, and it even arrived on the Metro – the newspaper on the tube every morning – that HIV was not going to be a problem anymore. The consequences of that title – it wasn't literally that title, but it was basically that there was a cure, that it was finished – the consequences of that title are devastating. I think the people who wrote that title should have been sued for putting people's lives at risk. And this, it's not only the scientists but the media needs to start having a high level of self assessment and have scientific consultants that can tell them yes or no, or go up to there" (UK1-3: researcher).

The second and third participants used examples related to other misuse of information. "So beyond bioterrorist approaches ..... There are all sorts of other ways in which information can be used inappropriately. So, for instance, the whole genetic screening issue, which is always very controversial if it also assesses things like ethnicity, racial inheritance, which can lead to discrimination" (UK1-8: HoD). They also used examples of HIV denialists and the harm resulting from their claims as examples why communicating with the public is important. This was made explicit by one participant who stated that: "[t]his [dual-use discussion] is feeding in to how terrorism works – by spreading terror. So you can already see by this discussion that people who talk about bioterrorism and its use are influencing how scientists think, so their ability to spread mistrust and lack of control is starting to work. So there has to be a worry about how much we play into terrorists hands by restricting things. If it's too much restriction then they've won and it stops us scientists moving forward to disease prevention research" (UK1-participant 6).

These discussions echoed a number of similar conversations had with African scientists where the "traditional" dual-use misuse of information was expanded on to include alternative stories of misinformation. In Kenya I was told on three separate occasions about an incident that had affected the laboratory when the first HIV vaccine trial was being launched. Misinformation to the public regarding the process and aims of the trial by popular newspapers<sup>91</sup> delayed the start of the trial by over half a year and necessitated considerable outreach to the community and government in order to rectify the situation.

In addition, many other stories of irresponsible journalism, public mistrust and deliberate misinformation involving scientific research were told by African participants. It was clear from the manner in which these stories were introduced and told that these events, and the consequences arising from them, were taken very seriously by these participants and viewed not only as a considerable hindrance to their future work, but also as a harm arising from its misuse.

The analysis of the fieldwork data thus demonstrated that different communities of scientists had very different reactions to the content of the harm principle that is generally proposed in dual-use education (without any accompanying discussion). While the UK scientists (with some reservations) were able to access the content and see its value and validity in relation to their research context, the African scientists I interviewed did not. Indeed, their (often violent) disagreement with the content made it very apparent that any educational initiative assuming that the content-full interpretation of harm would transfer easily across borders could run into trouble. These observations thus firmly emphasised the need to explicitly excavate the content of the harm principle within dual-use education.

<sup>&</sup>lt;sup>91</sup> Some of the articles claimed that the "foreign scientists" of the IAVI were deliberately infecting Kenyans with the HIV virus.

Nonetheless, during the fieldwork it also became apparent that an alternative, commonly accepted interpretation of the content of the harm principle in dualuse was recognised by the UK and African scientists. The agreed-upon harms arising from misinformation distribution and the responsibilities of scientists towards mitigating these risks provide an excellent alternative scenario from which to build dual-use discussion. Furthermore, in many African countries the science literacy of the general population is very low, which means that the harms arising from misinformation may be even more difficult to resolve than those in developed countries. These observations thus suggest that there are future opportunities to develop discussions in which African scientists will have a strong vested interest.

In a manner, liberating the idea of harm from its strict bioterrorism/biorisk content and instead allowing scientists to develop their own interpretations about misuse proved a successful means of developing discussions on dualuse. Once participants had established the link between the reuse of scientific information and the harm that could be caused to the general public due to misuse or negligence scientists proved more willing to engage with the concept of dual-use. This was observed at all fieldsites, both in the UK and in Africa, suggesting that if the content of "harm" and "maleficence" are explored instead of prescribed that meaningful dialogue can be established – which may show remarkable similarities at times.

# 4.5 <u>Conducting "Beneficial" Research</u>

Dual-use is concerned with the misuse of "beneficial" research, and it is thus obvious that understanding what is denoted by "beneficial" is of considerable importance in discussions. As will be examined below, one difficulty that I propose occurs during dual-use discussions is the lack of clarity that is made between the related terms of "beneficence", "beneficial" and "benefits". As each of these terms is related to specific content – which of course has the potential

to differ between moral communities - it is likely that considerable confusion can arise in this area.

When attempting to unpack the principle of beneficence, it is also important to observe that within ethical discussions, this principle is often presented in two contrasting ways. Beneficence could be taken to refer to the act of being good to others by positively acting in ways that serve their good. Alternatively, it could refer to the avoidance of maleficence, and thus arising from the absence of harm (Baggini 2007: 107). The distinction between the two forms of beneficence is important<sup>92</sup>, and is influential in many bioethical discussions (Beauchamp 2001, Baggini 2007).

Current definitions of dual-use usually utilise the term "beneficial research" to referring to the research under consideration. In most discussions this phrase is not explicitly unpacked, and is often merely taken as roughly equivalent to any life science research not intentionally created with aggressive purposes in mind. Nonetheless, this is a very vague designation and may ultimately prove problematic is one attempts to interrogate this principle in more detail. Indeed, in as much as the principle of "harm" is complicated by too much content, it would appear that the principle of "beneficence" suffers from too little. Thus, it is important to ask how, if at all, an international dual-use debate could reconcile itself to not only different interpretations of what it means to do beneficial research, but also to how value is attributed to the benefits arising from research.

Interestingly, within the dual-use ethics, there is rarely a clear distinction made between the two states of beneficence mentioned above, and both definitions of beneficence are employed within discourse (obviously to slightly different ends). The former interpretation could be taken to refer the duty of every scientist to conduct research deemed important for humanity to the best of their ability

<sup>&</sup>lt;sup>92</sup> It must be noted that the deontological ethics tends to focus on non-maleficence while consequentialist ethics tends to promote beneficence.

while avoiding the direct creation of harm through their research. Thus, the duty of beneficence involves conducting research that would benefit humanity as responsibly as possible. The imperative towards research that would benefit humanity marks the gradual shift away from the previous acceptance of the idea of "knowledge for knowledge's sake" as a justification for scientific research. Determining beneficence along those lines, however, is by no means straight forward, and an increasingly socially-orientated understanding of the value of science motivates considerable discussion<sup>93</sup>, and it is probable that *content-full* versions of beneficence in relation to scientific research will differ considerably between ethical communities. Nonetheless, dual-use discussions tend to lack any clarity on what exactly counts as beneficial – as opposed to value-less – research.

Such discussions of beneficence within dual-use are further complicated by the use of the term "beneficial" to refer to the original research. This can also be taken to refer to the *benefits* that may be expected from conducting the research, rather than from any moral association, and is thus closely linked to socio-cultural perceptions of the "good life". Understandably, the perception of the potential benefits of research has the potential to significantly affect how the research is critically assessed. It has been noted that on this front (especially within the dual-use debate), there has been a lack of critical benefit assessments of research, and nearly every biomedical experiment is, by default, considered beneficial (van Aken 2006). Indeed, as Jan van Aken of the Sunshine Project rather provocatively suggested: "as soon as hopes for a cure for life-threatening diseases are invoked – however putative, remote or hypothetical – scientific research is deemed justified" (van Aken 2006).

In contrast, the latter interpretation of beneficence revolves on the twin duties of beneficence and non-maleficence. Thus, by minimising harm one is acting beneficently. In dual-use discussions this interpretation would appear to refer

<sup>&</sup>lt;sup>93</sup> The value that different societies place on different streams of scientific research is by no means uniform. Such a tension exists, for example, in the transhumanism/human enhancement debate. It has been noted that much more value is attributed to this research in developed countries than developing countries.

particularly to the idea of beneficial research being *well-regulated* research. By ensuring that the research is, to the best of their abilities, compliant with the regulations that aim to prevent harm, scientists are ensuring that the research is beneficial.

Thus, if one critically examines the use of the principle of beneficence in dualuse discussions, it is apparent that the discourse is complicated by issues relating to the value placed on research, the intentions of the scientists, and the projected outcomes of the research – all of which, within a particular community, will be associated with specific content according to the sociohistorical context. Despite these complications, it is apparent from analysing dual-use discussions that the majority of emphasis lies on beneficial research referring to well-regulated research. Thus, research which is conducted in an open, transparent and responsible fashion. Less is said in these discussions about the value or potential benefits of the research.

In the fieldwork, as is discussed below, is appeared that this lack of clarity in the *content-poor* interpretation of beneficence, as well as conflicting *content-full* interpretations, led to considerable confusion, and impacted on subsequent dual-use discussions and the content that different moral communities prescribe to it.

## 4.5.1 The UK Says: We're Following the Rules ...

As mentioned above, at the beginning of each interview or focus groups participants were invited to briefly discuss their research. This often led to a related discussion on how they ended up in the field of HIV research. While the predominant response was a desire to contribute to an internationally relevant problem, many mentioned (with a degree of pragmatism) the financial benefits of working on a topical disease such as HIV. One participant mentioned that reasons for choosing HIV research are manifold, stating that: "one [reason] is

sheer pragmatism – it's easier to get a job working on HIV or flu than it is working on noroviruses or some obscure mixovirus, so there is a degree of pragmatism. The other side of it is, I do feel, that what they could potentially be doing could have an impact" (UK1-1: researcher).

Interestingly, none of the participants mentioned being personally affected by the HIV pandemic. Perhaps, as all the participants were European (where the HIV incidence is comparatively lower than most other regions of the world<sup>94</sup>), this was less surprising than if it had been a more multinational environment. For example, one participant, talking about how she got into HIV research said: *"I didn't know anyone who was HIV positive. So I haven't lived with the disease around me. I haven't experienced it, so it was pure scientific curiosity"* (UK1-4: researcher). As the UK site was my last fieldsite, I was definitely personally aware of how the lack of immediacy of the HIV pandemic within the UK promoted a different attitude in the laboratories to that in the African fieldsites<sup>95</sup>.

Despite a higher penetrance of ethics education within the UK science community, it is important to note that none of the UK fieldwork participants reported having had any formal ethics training during their under- or postgraduate education (apart from those courses relating to animal work or research with human subjects), and mainly confronted ethical issues on funding applications or REC submissions. It was therefore unsurprising that many of the initial discussion linked ethics to regulatory controls. As one participant put it, *"What I'm doing day by day doesn't have any ethical issues. I'm not working with human materials; I'm not working with animals. Most of the practices that we do in the lab are within health and safety"* (UK1-2: postdoc). Nonetheless, as another participant mentioned, *"[w]e cannot get away from the ethics because we do fundamental basic research, but it is difficult to see how far we can go."* (UK1-3: postdoc). From such responses it was deduced that scientists equated ethics with regulatory processes, and that they recognized that the

<sup>&</sup>lt;sup>94</sup> For a graphic representation see

http://www.unaids.org/globalreport/HIV\_prevalence\_map.htm (accessed 26/02/2013).

<sup>&</sup>lt;sup>95</sup> This is discussed in greater detail below.

regulatory climate in which they worked was not necessarily static and could necessarily change.

Linking ethics – and thus good practices in research - to regulation came up regularly in conversations with participants on all levels. Most of the participants commented on how the ever increasing regulatory environment complicated their daily research, saying things such as: "*Um, but, then again there are lots of limitations in everything we do anyway. There's the ethics, animal ethics, and there are limitations in some aspects. I think it's because it's a new area, type of limitation, that it seems restrictive at the moment."* (UK1-6: PI). However, not one participant questioned the need for a regulatory environment, or indeed that the regulations which governed their research assisted in prohibiting them and their colleagues from causing harm.

Notwithstanding the issues mentioned above, a critical analysis of the discussions that I had with participants at the UK1 site regarding beneficence in research showed that the responses predominantly tended to centre on the idea of *well-regulated* research being beneficial. Most of the participants did not have a personal connection to HIV, but viewed their research rather as an interesting academic problem or a solid basis for career progression. Because of this distinction, it would appear that when discussing beneficial research the participants were less concerned about the eventual benefits of an HIV vaccine, but rather concerned with *doing the research properly*. This relates strongly to the definition of beneficence as the avoidance of maleficence, as discussed above.

### 4.5.2 African Confusion: But I'm One of the Good Guys ...

In many of the initial interactions with scientists in the African laboratories (particularly those who did not attend the introductory seminar), there was a hesitation regarding the discussion of ethics. I jokingly divided this hesitation

into two different camps: those asking: "what have I done wrong?" and those asking: "what are you trying to stop me doing?". In both cases, there was a strong link between the use of ethics within research and biosafety. One participant in an SA1 focus group explicitly voiced this confusion, saying: "[h]ow do ethics play into it? I don't understand. If you're doing work on viruses, your ethics would be on animal work and stuff, and if you get approval then you're being ethical. Where does dual-use come in?" (SA1-12: participant 1).

I also had a number of conversations such as the one below where the participants would discuss research that could very easily fit into the spectrum of "experiments of concern".

LB: "Do you think the concept of dual-use has any importance in your work?"

SA2-7: "I don't know about my work, because my work is directed at therapy. Although I mentioned ... that RNA interference could be used as a genotoxin very easily. The one thing that we're developing is the NSS protein which yellow fever expresses. It's toxic and a unique protein in that the virus essentially kills the cell."

Interestingly, however, despite recognizing a dual-use potential in his work, the participant persists in creating a distinction between their work and dual-use based on their intentions. He further followed up the statement by saying: *"I hadn't really considered it until you brought it up - because I'm one of the good folk"* (SA2-7: PhD student).

This rhetoric of being "one of the good guys" was regularly used both as a justification for intentions and as an orienting tool for discussing the benefits of the research. In a field such as HIV research in Africa it is perhaps unsurprising that this topic of research was a personal motivator for many researchers, and many participants mentioned current HIV statistics, current problems with ARV

roll-out and unequal healthcare distributions as major contributors to their decisions to be in the field. It was interesting to note, however, that the personal motivations for research and the topic of research were frequently utilized in the acceptance or rejection of the concept of dual-use. The PI at SA1 quoted above backed up her dismissal of the concept of dual-use as Western paranoia by stating: "... we're in the business of curing AIDS, not making weapons" (SA1-8: PI). This comment also reflects what I perceived to be an undercurrent of urgency present in the African research – almost as if researchers were racing against time to find a cure.

This urgency also correlated to the often-repeated idea of "at the coal face" (SA2-5: HoD) in terms of disease research due to the considerable disease burden in the African countries visited. It was also important to note that the disease prevalence in these countries meant that many of the researchers had a personal motivation for research based on their experiences with the disease. Most of the participant that I questioned at the African laboratories explicitly mentioned a personal connection to HIV – either by knowing someone with the disease, or through the social climate of their culture. Indeed, at least two participants at each site mentioned that a friend or family member dying of AIDS contributed to their selection of their research topic.

Within all four fieldsites in Africa the immediacy of the disease to the researchers definitely contributed a different approach to research in comparison to the UK site. The potential benefits of an HIV vaccine were regularly and passionately evoked as a justification for research – and thus its beneficence. Although it would of course be binary to suggest that while the UK scientists were concerned with the process of research, the African scientists were focused on the benefits that could be accrued from their research, a tendency towards this distinction was definitely apparent from the fieldwork.

#### 4.5.3 Being More Explicit About Beneficence

Without doubt, all the participants interviewed for this project believed very strongly in the value of their research and the obvious benefits of an HIV vaccine. Furthermore, as evidenced by a number of quotes (such as *"I'm one of the good guys!"*), all of the participants genuinely appeared to be motivated by a desire to contribute to the generation of knowledge through research. However, when probed further, the concept of beneficence yielded some distinctly varying results.

While analysing the field results it appeared that there was a tendency for UK scientists to favour the idea of beneficence as an absence of maleficence – thus making their *content-full* interpretation of beneficial research *well-regulated* research understandable. To this end, a considerable amount of discussion was had on the nature of the rules governing dual-use, and their ability to guide and protect the research. In contrast, and probably largely to do with Africa being the epicenter of the HIV/AIDS pandemic, the African participants were considerably more concerned with the possible benefits of their research, particularly the utility of an AIDS vaccine, as a *content-full* interpretation of beneficence. Therefore they were more critical of regulations that they viewed as placing hurdles to goal attainment.

As mentioned above, it is of course unhelpful to classify these groups of scientists according to a binary division between the two interpretations of beneficence. However, such observations highlight the importance of not only paying careful attention to the *content-full* versions of ethical principles, but also clearly elaborating on their *content-poor* interpretations. In its current state, the dual-use debate is extremely ambiguous regarding what is denoted by "beneficial research" and the lack of a clear content-poor interpretation of this principle could contribute not only to communities of scientists misunderstanding each other, but ultimately talking at cross-purposes to each other.

# 4.6 Weighing Risks and Benefits: Where Does This Leave Discussions on Responsibility?

As the issue of dual-use within the life sciences has developed, there has been strong and prolonged support for preserving freedom and openness in research (as explicitly endorsed by the Fink and Lemon-Relman reports amongst others). As far as possible, current dual-use debates advocate for the self-regulation of the scientific community so as to avoid impacting on research processes by imposing additional regulatory structures. This has resulted in widespread endorsement of the model of "assisted autonomy" <sup>96</sup> first proposed by the Fink report (discussed in chapter two). In this model, scientists form the "first port of call" in identifying dual-use potential in their research, and bear responsibility for ensuring that the correct response structures are alerted.

Furthermore, the idea of scientists as the primary identifiers of dual-use concerns has also made an impact on the emerging discussions on dual-use bioethics, something which is evident from the papers on moral duties by Ehni and Kuhlau (Ehni 2008, Kuhlau 2008). As was discussed in chapter two, both promote duties for scientists that involve identifying and dealing with dual-use issues in their work. Such duties are also reflected in the use of the Precautionary Principle as an "ethical yardstick" for future dual-use initiatives (Kuhlau 2009)<sup>97</sup>, which places the responsibility for addressing the dual-use

<sup>&</sup>lt;sup>96</sup> Of course, as noted in chapter two, the idea of an autonomous body of scientists must be questioned – particularly in the USA where the NSABB plays an influential role in addressing dual-use concerns. However, for the purpose of this discussion, the idea of the scientific body being *encouraged* to address dual-use concerns within their research will be roughly equated to autonomy.

autonomy. <sup>97</sup> Within the dual-use debate, the precautionary principle is often employed to discuss the threat, uncertainty, prescription and action pertaining to harm and risks embodied in the dilemmas. A formulation of the precautionary principle has been proposed by Kuhlau et al, and states that: *"[w]hen and where serious and credible concern exists that legitimately intended biological material, technology or knowledge in the life sciences pose threats of harm to human health and security, the scientific community is obliged to develop, implement and adhere to precautious measures to meet the concern"* Kuhlau, F., Hoglund, A. T., Evers, K., Eriksson, S. (2009). "A precautionary principle for dual use research in the life sciences." Bioethics **25**: 1 - 8.

<sup>.</sup> They suggest that the suitability and success of a precautionary principle in dual-use research depends on the credibility of the threat, as well as the availability of evidence and qualitative information to enable some degree of possibility to foresee potential harmful outcomes Kuhlau, F., Eriksson, S., Evers, K., Hoglund, A. T. (2008). "Taking due care: moral obligations in dual use research." <u>Bioethics</u> **22**(9): 477 - 487.

risks of any research project firmly at the feet of the scientists who generate the data.

Thus, in contemporary dual-use discussions, the obligation of scientists to address the dual-use potential of their research is often both a regulatory and an ethical one. The message is clear: scientists bear a responsibility to identify and minimize the dual-use potential of their research. Indeed, this perceived obligation may be viewed as a role responsibility that has been developed by, and promoted widely in the Western dual-use community. Many of the current regulations depend on Pls (AAAS 2009). lead dual-use authors (Journal Editors and Authors Group 2003) or funding applicants to monitor their research for dual-use concerns and to report them to the relevant authorities.

It has been noted that scientists cannot be expected to adequately identify dualuse potential within their work without prior education on the subject (such as NSABB 2006), and indeed many initiatives aim at improving dual-use awareness in the scientific community. However, what these initiatives acknowledge but often fail to adequately address, is that identifying dual-use within one's own work involves both a personal evaluation of what may count as dual-use, and a risk/benefit analysis of the possible outcomes of the research.

If, as described above, scientists disagree with the proposed content of the ethical principles underpinning the concept of dual-use it is questionable whether they will agree with the risk/benefit analyses that drive the implementation of any control initiatives. Of course, it is difficult to understand

<sup>.</sup> Other authors, however, such as Steve Clarke, have questioned the limits of usefulness of the precautionary principle in the dual-use debate, suggesting the application of the principle depends on the adoption of a selective approach to risk Clarke, S. (forthcoming). The precautionary principle and the dual use dilemma. <u>On the Dual Uses of Science and Ethics</u>. B. Rappert, Selgelid, M. Canberra, Australian National University E Press.

<sup>.</sup> Clarke suggests that the use of applying the precautionary principle in such cases is very similar to conducting a cost-benefit analysis.

how far concerns regarding risks need to be extended. Are scientists to report only *likely* misuse, or are they (more in line with the approach proposed by McLeish and Nightingale) to speculate about where a convergence of technologies that includes their own could result in harm?

Furthermore, if they disagree with the proposed content of the dual-use concept, it is unlikely that any role responsibility assigned to them to conduct dual-use surveillance of their research would resonate on any meaningful level. Placing scientists in any position of surveillance requires that they not only understand, but also value both the risks and the benefits of their research. This section explores the idea of a risk/benefit analysis in greater detail, and how the practice of weighing risks and benefits played an important role in how the participants talked through their reaction to the concept of dual-use.

### 4.6.1 UK Says: As Long as Freedom of Research is Guaranteed ...

All of the participants interviewed at the UK site expressed concern at the idea of trying to control scientific information. This concern was linked to a frustration and disbelief at the feasibility of any such attempts. Arguments against any censorship and the need for free exchange of information in science were often dovetailed with the opinions that controlling information – particularly in this modern age – was futile, as access would always be acquired by interested parties. This reaction against censorship was considerable, and emphatic.

Interestingly, the rejection of control over research was linked by two of the participants to human rights and their suppression. It turned out that these participants had lived in Spain under the dictator Franco, which no doubt influenced their approach to censorship. One participant said: "*I was born in a country where they had a dictatorship, by Franco, and therefore you cannot break freedom of speech. That is one of the first things that you cannot attack.* 

So then how do you control information?" (UK1-3: researcher). While this response represented was one of the more extreme ones from participants at this site, the notion of rejecting censorship nonetheless was pervasive.

Another PI – despite being sceptical of the dual-use potential of life sciences research – made the following statement: "... I accept that there are some things that probably are irresponsible, um, but you don't necessarily want to be judged for what you're doing. You don't want to be limited in what you can do. Um, but, then again there are lots of limitations in everything we do anyway. There's the ethics, animal ethics, and there are limitations in some aspects. I think it's because it's a new area, type of limitation, that it seems restrictive at the moment." (UK1-6: PI). Thus, while he was not altogether convinced by the seriousness of the dual-use threat, he (in a similar manner to the rest of his colleagues) focused on whether any possible restrictions would be detrimental to their research. In this way, the risk to benefit calculation was made based on the need for regulation versus the possible disruption of research processes.

Thus, it appeared that many of the participants used their interpretation of beneficial research as *well-regulated* research (as discussed above) and their tendency to relate harm to biosecurity issues in their construction of a risk/benefit analysis. This prevalent attitude was succinctly summarized by the HoD, who said: "... dual-use is definitely important. How practical it is to monitor and control, and the balance between that and restricting information that could be of important benefit, is a very difficult balance to make. Unless you're working on something that could be clearly obviously used in an inappropriate fashion. So if you're working on plague or something that could already be used as a bioterrorist weapon then that's obviously going to be very different to working on technology that might have some tangential implication for misuse." (UK1-8: HoD).

This brief analysis showed two important issues. Firstly, and not surprisingly, that the risk/benefit analysis conducted informally by the participants in their

discussions of dual-use traded heavily on the prevalent *content-full* interpretations of beneficence and harm discussed above. Secondly, that there was largely unanimous support for the existing regulatory system and faith in its rationality and functionality. Thus, despite the hesitations voiced regarding censorship and lack of openness, it seemed likely that participants would widely regard any additions to the regulatory environment as a probable necessity. In this manner, the prevailing endorsement of the regulatory environment had a significant influence on the ethical position of these participants.

4.6.2 Africa Suggests: Tell Me What To Do and I'll Do It ...

When discussing the need for dual-use surveillance with the African scientists it was telling that the participants often minimized the risk of their research by balancing it against the possible beneficial outcomes. It was therefore apparent that in many cases the extent of the HIV pandemic in Africa influenced the manner in which African scientists approached the concept of risk and responsibility.

A number of participants in the KY1 site directly addressed this issue, suggesting that developing an HIV vaccine would minimize any possible dualuse risk in their eyes. One participant said that: *"The benefits of scientific research to Africa affects how people see risk"* (KY1-10 – participant 4), reaffirming the underlying implications of the different interpretation of *"beneficence"* discussed above. This was made even more explicit by another Kenyan technician, who said that: *"[b]ecause it [HIV] is such a big crisis, the risks [of our research] are outweighed by the benefits"* (KY1-3: technician). Once again, this tension between risk and responsibility was further elaborated by a Kenyan participant. During the discussion of dual-use in an African context he suggested that: *"Africa has such immediate problems that perhaps African scientists aren't as critical as they should be"* (KY1-10 – participant 1). This attitude of benefits outweighing risks was also reflected in the discussions on responsibilities for dual-use surveillance. A commonly echoed sentiment was that "... more administrative stuff ... would make my life hell. ... You can see I'm very anti this and it's not an issue for us" (SA1-8: PI). Another PI further elaborated on this theme, saying: "[i]t's just going to be more paperwork, more difficulties, and that's why they [the scientists] don't want to talk about it" (SA1-12: participant 2). The attitude of the risks arising from the research not justifying the regulatory efforts to address them were regularly revisited by many participants in both South African sites.

This tendency of making a connection between dual-use and bureaucratic difficulties was less pronounced in the Kenyan and Ugandan sites. While acknowledging that this could be an issue, fewer PIs explicitly mentioned the connection between funding and dual-use. It is interesting to note that both of these sites were funded in majority by a single, Western funding body (IAVI and MRC), and individual grants were less common within the laboratories. As will be discussed in later chapters, it is possible that the manner, mode and style of funding may affect how scientists interact with certain ethical concepts.

It would thus appear that the manner in which the risks and benefits of any sort of dual-use regulation was assessed by the African participants differed from their UK colleagues for a number of reasons. Firstly, their perceptions of the potential benefits of their research greatly outweighed their interpretation of risk (assisted, no doubt, by distancing themselves from the likelihood of risk arising from their research). Secondly, the African participants placed much less value on the perpetuation of an all-encompassing regulatory structure to govern their research. Thus, the addition of new regulations would not seamlessly integrate with existing regulations, and thus were perceived to have the potential to cause major disruptions. Thus, it would appear that many of the African participants firmly promoted the idea that the benefits of regulating and addressing dual-use concerns in scientific research could not be justified by the potential loss of research output benefits that would affect the HIV pandemic.

#### 4.6.3 Putting Value into Risk/Benefit Analyses

The idea of openness in research is a complicated subject. Despite an almost universal support for openness and freedom in scientific research, it is becoming increasingly unlikely that the possibility of absolute freedom without any restrictions or regulations can be anything more than an ideal. Instead, most scientists are becoming reconciled to the presence of some regulations governing their research. Nonetheless, as was evident from the fieldwork, whether they see value in these regulations depends on their interpretations of the risks and benefits that these regulations are governing.

Amongst the UK participants I perceived a high level of endorsement for the existing regulatory system that appeared to echo the general perception of beneficence in science indicating *well-regulated research*. Thus, when weighing the risks to the openness of science from increased dual-use regulations against the benefits of these regulations, it appeared that many participants were willing to accept additional regulations if they were integrated into the existing structures. Notwithstanding many participants expressing a degree of scepticism regarding the feasibility of any dual-use control, it was notable that more of the participants discussed *what* controls should be developed, rather than *if* they should be developed at all.

Within the African fieldsites, in contrast, the general dissociation from the dualuse concept meant that participants were much more sceptical not only about the feasibility of dual-use regulations but the value of any such regulation with regards to their research. In particular at the South African sites the PIs and research scientists regularly made connections between increased regulations and disruption to their work. Furthermore, the concurrent distancing from the issue of dual-use ("it's not my problem") resulted in some of the interviewees becoming extremely agitated at what they perceived to be the imposition of unnecessary regulations. Indeed, one PI referred to the recent security questions on funding application forms as *"just another hoop that we have to jump through"*. Thus, the lack of buy-in of the concept of dual-use, together with the absence of local governmental support for these initiatives resulted in a number of the South African PIs and researchers voicing their opinion of the securitization of scientific research as an unnecessary bureaucratic exercise. Furthermore, as the participants evidently had a different ethical content for the principles underpinning these regulations, these security initiatives lost potency and tended to be viewed as "tick-box" exercises necessary as a means to an end, and not as a valuable element of research preparation.

This brief analysis of how scientists calculate the risks to the freedom of their research associated with further regulations against the benefits to be gained from a secure research environment suggested that a general endorsement of dual-use as a concept, and a motivation for further regulating research, cannot be assumed. In particular, this chapter suggests that by excavating the content of the ethical principles underpinning the dual-use discussions provides a clear indication of possible differences in approaches to risks and benefits, and their attitudes to the imposed regulations. It would thus appear important to explicitly consider what assumptions the dual-use debate is making, in order to better understanding *what exactly* we are asking the science community to accept. These include the acceptance of bioterrorism as a realistic harm, when are the benefits of scientific research realistically jeopardized by such harms, and how such harms can be mitigated through possible controls of information.

# 4.7 The Content of Ethical Principles and Dual-Use Pedagogy

By combining the theoretical analysis offered at the beginning of the chapter with the results from the various fieldsites it is possible to build up a multifaceted understanding of one element of discord in the dual-use debate: that a lack of attention to the varying content of ethical principles causes difficulties when attempting to engage scientists from differing contextual backgrounds. As many dual-use discussions often tend to promote the impression of a global secular bioethics, they do not explicitly engage with the possibility that the content of ethical principles may vary considerably according to the moral community in which the principle is being applied. However, the discussions occurring during the fieldwork strongly suggested that such an approach may prove detrimental towards fostering dual-use awareness – particularly amongst African scientists.

This situation is further complicated by my proposal that most dual-use educational initiatives continue to present a traditionally Western interpretation of the key ethical principles involved in the debates as *fait accompli* that requires no content excavation. Indeed, this approach was mimicked in my own fieldwork, and the introductory seminar and information sheets (as can be seen in the appendices) presented a rather generic and popularist interpretation of the dual-use concept. This approach was further enforced by my choice of a review by Taubenberger on his 1918 flu research as the focus group text. This research, as one of the classic "experiments of concern", is indeed an example of dual-use concern at its most extreme.

Nonetheless, this approach paid dividends, and it was enlightening to see how participants interacted with the concept – one which none of them had ever explicitly encountered – and deconstructed it and offering their own interpretations as to its validity. As mentioned at the beginning of this chapter, the work of H. T. Engelhardt offers a valuable means of framing both the process of deconstruction and reconstruction that was witnessed during the fieldwork. By using the distinction between *content-poor* and *content-full* versions of ethical principles it is possible to discuss in some detail why exactly some communities of scientists were able to access the concept more easily than others.

Thus, one must ask, are current approaches to dual-use ethics pedagogy hampered by their (apparent) promotion of a global, secular ethics and a
relative absence of discussion on the possible content variations of ethical principles. In particular, can codes of conduct be effective without significant discussion regarding how the *content-poor* and *content-full* interpretations of the principles are understood within a specific context? Judging by the fieldwork results presented above, it would appear that dual-use ethics initiatives are undermined by the absence of such dialogue – particularly in developing countries.

Despite the recognition of this problem, however, visualising a feasible alternative remains difficult. Engelhardt, in his attempt to resolve conflict between different principles (such as beneficence and non-maleficence, for example), proposed that autonomy be placed in a position of supremacy over all other principles. Thus, what remains most important is to allow moral communities the opportunity to develop and interpret their own understanding of issues and their ethical reaction to them. However, this is often accused of straying dangerously close to relativism, although the inter-community acceptance of certain *content-poor* principles as being of importance to a particular issue serves as a unifying means of addressing disparate communities.

In a manner, dual-use education is already doing this. By endorsing the idea that no one size fits all in ethics education, dual-use has opened up the possibility for contextually applicable and pertinent educational courses to be developed by scientists "on the ground". In such a case, it is hoped that the *content-poor* principles presented in codes of conduct and in lists during lectures may be interrogated and discussed to provide meaningful interpretations for students<sup>98</sup>.

<sup>&</sup>lt;sup>98</sup> Of course, this is associated with another problem – with the increasing pressure to create international systems of dual-use controls, scientists will be increasingly expected to conform to dual-use controls and requirements regardless of the *content* that their particular ethical community prescribes to it. This is another complicated series of problems and will not be discussed here.

Unfortunately, as has been recognised repeatedly by many authors, ethics education for scientists at the moment remains patchy and unstandardized (Mancini 2008). Thus, the competent translation of *content-poor* principles into contextually relevant *content-full* ones cannot be automatically assumed. Moreover, as in many cases the sole interactions that scientists have with dualuse ethics is through bureaucratic requirements, online courses or codes of conduct, one must question whether there are other ways in which this current problem can be overcome.

From the fieldwork I feel that what united all the scientists in their diverse work settings was a genuine desire to contribute to the good of humanity through their personal research efforts. Whether this was motivated by a belief in the importance of high quality research, or a strong personal desire to confront the HIV pandemic, all the participants possessed a emphatic belief in the importance of their research and the potential benefits that it would contribute towards humanity. Thus, the persona of a caring and compassionate scientist definitely transcended cultural specificities.

It would thus appear to me that dual-use could be repositioned to be an element on discussions about what it means to be a "moral scientist", and how best to embody a duty towards caring. It is possible that by allowing scientific communities to independently deconstruct what they determined to be important contributing factors towards their overriding obligation to care may make such discussions more accessible to communities of scientists around the world. By connecting broad social issues such as dual-use to different interpretations of what it means to act virtuously in research it is possible that these issues will become more international.

Of course, attempting to translate the ideal of "moral citizenship" into a pedagogical initiative is by no means an easy task – particularly in light of the existing limitations in ethical education for scientists. Indeed, the notion of "moral citizenship in scientific research", as the facilitator towards scientific

research that benefits humanity, requires careful and extensive consideration. Furthermore, what can be understood as a moral community within scientific research and whether this is indeed a useful term in ethical discussions remains to be further interrogated.

It is obvious that these issues suggest a repositioning of dual-use ethics into the camp of virtue ethics, as discussions of virtues and the aims of science become particularly important in the development of the idea of a "moral citizenship in scientific research". This, as suggested earlier, will be discussed at length in chapter seven which consolidate the findings of the fieldwork in a review of possible new avenues for ethical teaching in science. However, in order to properly lay the foundations for this proposal it is necessary to introduce the second areas of fieldwork investigation.

# 5 <u>Assigning Role Responsibilities for Dual-Use</u> <u>Control: Help or Hindrance?</u>

The previous chapter examined some problems associated with introducing scientists to the dual-use debate, and their ability to access the ethical principles that underpin the concept. Although understanding and valuing the concept of dual-use is the first important step towards raising dual-use awareness, it should nonetheless never be considered the only one. This chapter examines another vital stage in raising dual-use awareness: incorporating ethics into daily research. The possible problems associated with this were elaborated on in chapters one and two, focusing on the lack of sensitivity to the physical environment in which scientists conduct their research.

In his seminal book *Laboratory Life: the Construction of Scientific Facts*, Bruno Latour makes an extremely insightful statement. He says: "[s]ocial studies of science and philosophy of science tend to be abstract or to deal with well known historical events or remote examples that bear no relationship to what occurs daily at the laboratory bench or in the interactions between scientists in the pursuit of their goals. In addition, journalistic or sociological accounts seem sometimes to have the sole purpose of proving merely that scientists are also human" (Latour 1986: 11). This quote succinctly highlights the dangers of overlooking daily practices in scientific research. Indeed, as he suggests, it is too easy for sociological and philosophical studies to reduce research practices to an abstract ideal, thus becoming unreflective of the fields they wish to comment on. By making sweeping statements about scientific research, many studies run the risk of overlooking the complex and varied minutiae of daily research life.

When considering ethics research in the life sciences, these observations become (to my mind) particularly pertinent. How and why scientists act as they do within their daily research practices cannot be reduced simply to a personal

moral compass. Instead, it is important to consider that conflicting regulations, behavioural practices, and problematic areas in the research environment all have the potential to significantly alter how and why scientists behave as they do in their daily research. Ethical research is dependent both on environments conducive to ethical behaviour – and it is important to note that such environments include social, regulatory, and physical elements.

In this chapter the regulatory-physical environment is examined in more detail. Although this has not been the specific topic of many studies within life science bioethics, it has nonetheless been the subject of studies in related areas that can be used in these analyses. For example, in the field of medical ethics recent research conducted by Daniel Chambliss amongst hospital nurses suggested that conflicting expectations, requirements or regulations by different bodies of power in their daily working environment caused distress which became perceived as "ethical problems" and led to considerable ethical distress. Using this and related research, chapter questions whether discordances within the fieldwork environments led to (conscious or unconscious) distress amongst participants that ultimately contributed towards ethical fatigue or erosion.

Particularly in relation to dual-use, the chapter examines how the role responsibilities discussed in chapter two are often taken to be universally applicable responsibilities, and not (as I suggest) highly dependent on the research environments in which they are to be enacted in. As I questioned in chapters one and two, is it possible that neglecting to discuss the regulatory, social and physical elements that go into the development (and subsequent fulfilment) of role responsibilities potentially alienating scientists from discussions on dual-use? Thus, as this chapter questions, is it possible that issues such as biosafety and security measures, national buy-in and support for dual-use initiatives, regulation and funding for research by government all affect the manner in which the concept is perceived and embraced by scientists? Furthermore, is it possible that overlooking the influence of the structures in place to assist in research, such as waste disposal, energy supply, transport

and border controls might significantly alter the success of any educational initiative?

The chapter then goes on to examine how feelings of individual responsibility can be undermined by the inability to follow the rules – in a situation where rule following is roughly equated to individual responsibility. Furthermore, it speculates on how these disjunctions between the expected and possible behaviour may detract from a sense of collective responsibility due to its presentation as an aggregate phenomenon, as discussed in chapter two.

# 5.1 <u>A Research Environment That Facilitates Responsible</u> <u>Behaviour</u>

In this chapter a distinction is made between the social environment of the laboratory and the regulatory-physical environment of the research facility. Such a differentiation is rarely made, and indeed many influential reports which have assessed research environments (such as IoM 2002) usually consider the research environment as a whole. However, I believe that such a distinction is helpful when considering broad social issues. Indeed, by contrasting the issues arising from this chapter with those presented in chapter six (which deals with the social environment of the laboratory) it will become apparent that these two aspects of the research environment present very different complications.

This section elaborates on what I refer to as the regulatory-physical environment of the laboratory, and highlights the considerable amount of variations between laboratories. It then goes on to present a case for how discordance within this environment may influence how responsible behaviour is perceived by scientists as well as by the greater science community.

### 5.1.1 Visualising Daily Life in a Life Science Laboratory

Despite entrenched myths of science as a solitary pursuit, modern scientific research is anything but isolated or antisocial. Indeed, a growing number of sociological studies into scientific research<sup>99</sup> attest to the frenetic pace and highly varied activities that epitomize laboratory research. To be a successful scientist, as one of my mentors used to say, you need to be a politician and a multi-tasker *par excellance*.

My personal experience as a cell biologist has made me very aware of the multifaceted dimensions of conducting scientific research and "being a scientist". Daily research, despite perceptions to the contrary, is not comprised solely of sitting at a desk planning experiments that are then conducted at the laboratory bench. Rather, each day includes flurry of bureaucratic and practical tasks including ordering (and following up orders of) reagents; maintaining or organizing maintenance of equipment; writing, administering and following up grant applications; submitting ethics approvals; and complying to a myriad of regulatory requirements stemming from institutional, governmental, funding or international policies.

In addition, most scientists have to deal with the little mentioned minutiae of laboratory duties, including sorting, bagging and disposing of waste; storing and documenting samples; maintaining numerous registers – including accident reports, health and safety checks, reagent lists, and dangerous materials lists. Thus, in contrast to a relatively tranquil picture of the "scientist at his bench", a peak into any laboratory will instead present a picture of constant activity in a dynamic environment that makes many demands on the individual scientist.

<sup>&</sup>lt;sup>99</sup> Of course, the seminal work in this field is Bruno Latour and Steve Woolgar's 1986 book *Laboratory life: the Social Construction of Scientific Facts.* This was one of the first studies to critically examine the environment in which scientific research takes place, and the effect that it has on the construction of knowledge.

Recognising this multifaceted environment, however, is not without its problems, and representing the numerous social networks, regulations and physical environment that make up a laboratory is difficult. Moreover, extending any such model so as to reflect the laboratory's position in the greater scientific community presents further challenges. Recently, the Institute of Medicine published a report entitled *Integrity in Scientific Research* which make use of the Open Systems Model (OSM) (IoM 2002) as a means of conceptualising modern laboratories. This model originated in business ethics and depicts social organization as involving many different elements including an external environment, organizational divisions, individuals and reciprocal relationships between all of them (IoM 2002: 50).



Figure 2: My adaptation of the OSM to reflect the regulatory-physical environment

In the diagram above I have adapted the traditional OSM model used in the Institute of Medicine report to reflect the multiple areas of the regulatoryphysical environment that play a role in daily laboratory research, and which I propose to be important in ethical discussions. This representation clearly shows the dynamic flux of elements relating to research, and how the laboratory channels (and is framed by) many different processes, including a variety of inputs and outputs. Many of these processes occur simultaneously in a number of different environments – including the laboratory, institutional and external.

This model thus succinctly represents the characteristic of scientific research that I described above – that it is a dynamic system continuously interacting with its environment through information, energy, or material transfers into or out of the system boundary.

### 5.1.2 Acknowledging Variations in Laboratory Structures

If one examines the diagram above, it becomes apparent how variable research environments can be. If they are, as suggested, made up of a plethora of different processes, then it stands to reason that each laboratory will have unique features in its research environment based on the variety of combinations available. Such an observation of variations within laboratories can be held valid for considerations on all levels – from international comparisons to those within a specific institution.

In this chapter the regulatory-physical environment will be examined in detail. By the regulatory-physical environment I refer to those regulatory (institutional regulations and national legislation) and physical (equipment, and processes mediating inputs and outputs) elements found in the laboratory, institutional and national environments (as detailed above) that together contribute to the idiosyncrasies of a particular research environment. If, as I will suggest, the regulatory-physical environment in which research is conducted has the potential to influence the behaviour of the scientists operating within it, it becomes feasible to suggest that the variations in this environment could have a significant influence on how ethical responsibilities are conceptualised and acted upon. It thus appears important to ask why the regulatory-physical research environment does not get more attention in philosophical, ethical and sociological studies, as the *ability* to act upon a moral (or role) responsibility is an important a consideration.

Such a question no doubt has many different facets; however it is my opinion that one of the most significant aspects to consider is the relative maturity of these environments in developed countries (where much of current life science ethics originates). In countries where the regulatory-physical environment is extremely comprehensive and highly standardised, it is understandable that the primary focus of social science studies would be on the social environment of laboratories and their contribution to misconduct. Thus, many aspects of this environment, such as waste disposal; border controls for export and import of samples and reagents; power, internet and communication facilities; core funding for laboratories and essential maintenance of laboratory equipment are little discussed precisely because they are well provided for.

Such speculation may similarly be applied to governmental involvement in scientific research. Although this is of course a continual topic of debate, and national variations in science regulation are often the topic of dissention, similarities in the focus of many of these regulations and the requirements they make of the research ensures the existence of a coherent system of regulatory guidelines and structures in most developed countries<sup>100</sup>.

Nonetheless, it is important to remember that such assumptions cannot be made for all scientific communities. As discussed in section 3.2.1.1, the regulatory-physical environment presents considerable challenges to researchers in some regions such as Africa. To briefly recap, inadequate resourcing and lack of core institutional funding; lack of governmental support and control; poor service delivery infrastructure (internet, electricity, water etc); and poorly developed biosafety and biosecurity regulations all contribute

<sup>&</sup>lt;sup>100</sup> Of course no regulatory system is perfect, and undoubtedly every country has its problems. Nonetheless, the existence of a regulatory framework is definitely an aspect of scientific research in developed countries.

towards very different research environments to those in the West (Kirigia 2005, Fine 2007).

It is both the lack of attention to these environmental variations in academic research and policy development, and the concurrent drive to increase the global presence of African science (Nordling 2010) that prompts this chapter to question whether these influence how and why scientists discuss individual and collective responsibilities in scientific research. In particular, in light of the emergence of role responsibilities as a means of communicating specific behavioural expectations to scientists for broad social issues, this chapter asks, are the disjunctions between the regulatory responsibilities and the possible behavioural outcomes causing not only practical but also ethical discomfort amongst the scientific communities?

#### 5.1.3 Laboratory Structures and Responsible Behaviour

It would therefore appear that current ethical discussions are faced with a number of interlinked problems relating to responsible behaviour in scientific research - particularly that the role responsibilities developed in Western countries may cause practical - and ultimately possibly also ethical - problems if transposed into non-Western nations. These problems, while pertinent for consideration in international research ethics, are compounded in the field of broad social issues. In particular attempting to promote the application of specific interpretations of role responsibilities across borders discussions tends to neglect the specific context in which these responsibilities are developed and applicable. While, as I suggested in chapter one, this is not necessarily of critical importance to discussions on research ethics, this becomes a vital consideration for broad social issues due to the highly contextualised nature of these issues. Not only could these role responsibilities not reflect the social contract between scientists and society in different contexts, but furthermore it is highly possible that any disjunctions between expected and feasible behaviour may exist due to considerable variations in research environments.

Thus, these role responsibilities may impact on the ethical development of scientists in these regions.

As displayed above in the OSM, it is important that when critically assessing these issues that the research environments under discussion be considered *beyond* the borders of the laboratories and institutions. What effect, for example, could the absence of adequate waste disposal systems, when contrasted against the conventionally-presented USA role responsibilities elaborated on in biosafety training and funding requirements, have not only on the integrity of the research, but also on how the scientists perceive and act upon their perceived responsibilities? Such considerations are uncommon for life science ethics, and it is thus helpful to draw on recent research in other fields of ethics to better flesh out these issues.

A number of different studies have already considered how the working environment contributes to, or detracts from, ethical behaviour and responsibility amongst those working in it. These include studies in the areas of business ethics (Trevino 1986, Trevino 1990), medical ethics (Christakis 1993) and also within life sciences research (Ladd 2009). Indeed, the Institute of Medicine publication *Integrity in Scientific Research* specifically highlighted the contributions that the institutional environment makes towards ensuring research integrity. The report emphasized the need to consistently and effectively provide training, policies and procedures as well as tools and support systems to facilitate responsible conduct within research (IoM 2002: 4).

Although these studies are largely concerned with the influence of the social culture on ethical development, they provide important points for consideration. Firstly, it is possible that a lack of sensitivity towards the specific nature of their regulatory-physical environment may result in the imposition of regulations, duties, or role responsibilities that are at odds with existing regulatory structures in the laboratory. For example, foreign funding may come with specific biosafety regulations that prioritise different aspects to those *in situ*. The idea of

competing systems of priorities has previously been well examined in medical ethics, particularly in the work of Daniel Chambliss.

In his 1996 book Beyond Caring: Hospitals, Nurses, and the Social Organisation of Ethics, Chambliss examined ethical agency amongst nurses in hospitals (Chambliss 1996). He proposed that many problems seen as ethical dilemmas actually arise when groups of two professions clash; when occupational groups have different motives; or when "the system" thwarts the efforts of certain people to do what they see as their job. Therefore he suggests that when considering problems that may appear to be ethical in nature it is important to consider the groups involved in the problem and their motives. Indeed, it is possible that many problems which are assumed to be ethical dilemmas are not merely a competition of ideas, but also a competition of people who have their various goals and methods (Chambliss 1996).

Chambliss' work could thus be extended for use in the life sciences. Particularly relating to scientists in developing countries, it is important to question whether the role responsibilities generated by funding, publishing and social pressures in developed countries thus present competing systems of priorities when applied in developing countries. In particular, are the competing ways in which (often very similar) practical requirements are embodied in policy documents appearing at the heart of many perceived ethical confusions? Is it possible that being more explicit regarding the different obligations and requirements imposed on scientists on the international, national and institutional level may neutralize some of these issues?

Secondly, it should be considered whether the inability to fulfil these role responsibilities due to deficiencies in their research environment might lead these scientists into a situation similar to anomie<sup>101</sup>, where a general ethical

<sup>&</sup>lt;sup>101</sup> The concept of anomie was first popularized by the French sociologist Emile Durkheim in his influential book Suicide (1897). Anomie describes a lack of social norms and the breakdown of social bonds between an individual and their community. Importantly, it also refers to the ethical dissociation that individuals experience when unable to access the benefits of society by

fatigue causes them to dissociate themselves from the regulatory systems and cease to see value in its objectives. Furthermore, it is possible that these insufficiencies of the regulatory-physical environment cause scientists to be excluded from engaging in internationally sanctioned (and thus "acceptable") behaviour through legitimate means. This may lead to deviant behaviour, of course, but it could also degrade perceptions of membership to the international science community if, as discussed in chapter one, membership is based on an aggregate approach of "everyone pulling their own weight".

It would therefore seem that the regulatory-physical environment of laboratories has the potential to significantly influence the success of dual-use education and the implementation of control initiatives. Thus, in light of the emerging trends towards global harmonisation of biosafety, biosecurity and dual-use initiatives, one must question how best the responsibilities of scientists may be presented so as to take into account the differences between regulatoryphysical environments.

# 5.2 <u>Being "Responsible" for Dual-Use in a Specific</u> Regulatory-Physical Environment

Within current dual-use debates, the possible variations in the regulatoryphysical environment of research are rarely explicitly discussed. Nonetheless, it is likely that refocusing these discussions to include issues relating to variations in the context of scientific research may have important consequences for future attempts to "globalise" dual-use awareness and control.

In particular, as the discussion above has suggested, the regulatory-physical environment can have an extended and pervasive influence on ethical development of those working within it. Thus, it is likely the regulatory-physical

legitimate means, resulting in fragmentation of social identity and rejection of self-regulatory values.

environment will prove particularly pertinent for the development of dual-use ethics, as well as the international implementation of dual-use controls. Furthermore, as is evident from chapter two, discussions on dual-use regulation, the web of prevention, and the role responsibilities that are emerging for scientists with regard to dual-use control have a prominent part in any awareness-raising initiatives. Nonetheless, currently most dual-use educational modules do not explicitly interrogate the practicalities of exercising dual-use responsibility within a specific regulatory-physical environment. Is this, one must ask oneself, a problem?

An examination of the development of dual-use discussions suggests that there are two key issues that have contributed to the low level of attention that these variations in the regulatory-physical environment currently receive. Firstly, it would appear that the "web of prevention" model, despite recognising the significant national variations in implementation, continues to promote role responsibilities for scientists which are aligned to a Western, developed regulatory-physical environment and which is rarely specifically discussed. Secondly, the close relation between dual-use and biorisk management have potentially caused the recent developments towards the global standardization of regulatory-physical environments to address biorisk concerns to overshadow specific dual-use requirements. These two issues are discussed in some detail below.

In section 2.2.1 the "web of prevention" model was discussed in some detail. To briefly recap, the model provides a middle ground between traditional arms control or voluntary self-governance (Harris 2008: 147), and outlines a structure of multiple, interdisciplinary yet interlinking initiatives which together distribute responsibility for, and expertise in, dealing with aspects of the dual-use potential of the life sciences. It involves multidisciplinary partners including the security community, public health systems, governmental bodies including customs agencies and the scientific community which are involved in a plethora of activities including export controls, disease detection and prevention, effective

threat intelligence, biosafety and biosecurity initiatives, international and national prohibitions, oversight of research, and education for life scientists<sup>102</sup>.

This model has proven influential in recent debates on dual-use control, and has provided a flexible framework by which national dual-use response initiatives can be comparatively understood<sup>103</sup>. The "web of prevention" model has also played a significant role in the current developments to address the individual and collective responsibilities of scientists for the dual-use potential of their research. Importantly, it is vital to note that this model explicitly promotes relieving scientists of sole responsibility for the dual-use potential of their research, and redistributing this responsibility through the collaborative efforts of the other partners.

Within dual-use ethics and education, the "web of prevention" model has also been influential, as it has provided a convenient means of detailing the different levels of responsibility for dual-use control to learner scientists. Using this model it is possible to schematically illustrate how the different areas all contribute towards a broad base of control, while positioning the responsibilities of scientists within this "web of prevention". Based on the idea of distributed responsibility, ethicists such as Kuhlau and Ehni have proposed a number of different duties for scientists (as discussed in section 2.2.3), including the duty to prevent bioterrorism, to oversee access to dangerous materials and to report activities of concern (Ehni 2008, Kuhlau 2008). These, or similar, duties have become a staple part of many dual-use awareness-raising initiatives – all of which promote the vision of an engaged scientist operating within a broader environment of distributed dual-use control.

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http://www.brad.ac.uk/bioethics/EducationalModuleResource/EnglishLanguageVersionofEMR/ See lecture 21. Accessed 14/03/2012.

<sup>&</sup>lt;sup>103</sup> Indeed, "web of prevention" discourse explicitly recognizes that no "one size fits all" and that different nations will have differences in their implementation of the "web" based on their national priorities and capabilities. For a good review of these national characteristics, see the edited volume by Brian Rappert and Catriona McLeish (2007). <u>A Web of Prevention</u>. <u>Biological Weapons</u>, Life Sciences and the Governance of Research. Science in Society Series. London, Earthscan.

What is not raised in these initiatives, or in the surrounding ethics discussion, is the recognition that these duties (or role responsibilities) are premised on a specific regulatory-physical environment that has certain characteristics. For example, the duty to report activities of concern obviously requires someone to report the activities to, and a system that can actively react to these reports. If one becomes aware of these requirements, it becomes impossible not to view these role responsibilities as being premised on the presence of a certain interpretation of the regulatory-physical environment that may, in fact, not reflect research environments around the world.

My personal examination of a number of dual-use modules, as well as conversations had with a number of dual-use educators suggested that within these educational courses references to the regulatory-physical environment predominantly relate to national or institutional biorisk regulations, and emerging national biosecurity guidelines, and tend to overlook the minutiae of daily research life (the "inputs" and "outputs" described by the OSM). In the absence of any in-depth focus groups or interviews, of course, it is difficult to see how the details of daily research life could be addressed in any meaningful manner. Thus, one should ask what effect introducing such role responsibilities without an accompanying discussion on the regulatory-physical environment is having on scientists from developing countries. Could such role responsibilities be met, and if not, what practical, moral or legal implications would these have for scientists in these environments (Bezuidenhout 2012)?

The absence of discussion about the possible variations in the way in which scientists interact with role responsibilities is no doubt also further complicated by another characteristic of many dual-use educational initiatives: the explicit promotion of an international approach to dual-use awareness and control. The influence of reports such as the Fink and Lemon-Relman have focused considerable attention on the idea of a global community of scientists who work cooperatively to minimize the dual-use potential of the life sciences. It is my opinion that promoting this laudable goal in conjunction with discussions on the "web of prevention" presents rather a confusing picture to scientists. Without

reference to the regulatory-physical environment of the individual researcher it is possible that scientists may feel unable to fully engage with their proposed responsibilities, leading to considerable confusion (in a similar manner to that described by Chambliss above).

Interestingly, it must be noted, such concerns extend beyond educating scientists about broad social issues, and are also applicable to research ethics and the establishment of international standards for biological safety. In my personal experience both as an African life science researcher, and while conducting the fieldwork for this project I have been made aware of the disjunction between what "should be done" and what "can be done". I have regularly heard the lament of *"we'd like to do that, but we can't, so what should we do instead?*" from scientists regarding international standards and foreign SOPs.

Nonetheless, as discussed in chapter one, there is a widespread and growing international commitment to improving biosafety and biosecurity. This is evident in most areas of the world, with the emergence of national, regional and international biosafety associations, and the production of international statements on biosafety and biosecurity<sup>104</sup>. This international focus and

<sup>&</sup>lt;sup>104</sup> Biosafety is generally thought to include "the development and implementation of administrative policies, work practices, facility design, and safety equipment to prevent unintended transmission of biological agents to workers, other persons, plants, animals and the environment" UNAS (2008). Promoting Biosafety and Biosecurity within the Life Sciences: an International Workshop in East Africa. Kampala, Uganda, Uganda National Academy of Sciences.

<sup>.</sup> Biosafety practices include containment principles and technologies as well as waste disposal strategies AAAS (2009). A Survey of Attitudes and Actions on Dual-Use Research in the Life Sciences. Washington D. C., American Association for the Advancement of Science and the National Research Council.

<sup>.</sup> These may, in turn, be translated into a number of biosafety obligations, including the appropriate usage of protective equipment and clothing, safe handling of materials in laboratories, safe operation of equipment, safe disposal of materials, safety management and accountability, hazard assessment processes, safe transportation of materials between laboratories, safe design of facilities, emergency responses, safety education for personnel, and applicable government regulations NAS (2009). On Being a Scientist: a Guide to Responsible Conduct in Research. Washington DC, National Academies Press.

<sup>.</sup> Biosecurity, on the other hand, involves the "protection of high-consequence microbial agents or toxins, or critical and relevant information, against theft or diversion by those who

increasing pressure for the standardisation of biosafety practices has necessitated that governments around the world take measures to revise the regulatory-physical environment of scientific research so as to ensure that they conform with international standards. Thus, while being aware of the variations in the regulatory-physical environment remains a consideration for biosafety discussions, in this area it is perhaps less discussed because of emerging widespread similarities and the belief that *something is being done*.

Such a situation, however, cannot be taken for granted in the development of dual-use controls. Thus, it is possible that by making the explicit link between efforts to internationalise dual-use initiatives and international biosafety regulation scientists may have an inflated idea of the feasibility of internationalizing dual-use controls. Furthermore, as discussed in chapter two, in many cases dual-use controls do not form a separate body of regulation, but rather an additional element of surveillance on top of existing structures, which may also contribute towards the lack of attention to the regulatory-physical environment. Nonetheless, it should be apparent (as is obvious from the previous footnote) that the regulatory-physical environmental requirements for biosafety and biosecurity are not identical to those being made for dual-use. Thus, can a *laissez faire* attitude be condoned in dual-use discussions simply because biosafety initiatives are improving around the world?

*intend to pursue intentional misuse*" UNAS (2008). Promoting Biosafety and Biosecurity within the Life Sciences: an International Workshop in East Africa. Kampala, Uganda, Uganda National Academy of Sciences.

<sup>.</sup> The objective of laboratory biosecurity is to safeguard materials, employees, information and other laboratory assets Clevestig, P. (2009). <u>Handbook of Applied Biosecurity</u> for Life Science Laboratories. Stockholm.

<sup>.</sup> Thus, cultivating an awareness of security within life sciences research includes activities such as employee accountability, material control, development of standard operating procedures, compliance with biosecurity procedures, physical security, access control, information security, transport security, proper routines for security-incident reporting and response, maintaining continuous evaluation and revision as well as providing training and education ibid.

It therefore seems likely that the influence of the regulatory-physical environment in developing a global culture of dual-use awareness is overlooked precisely because it is *already in place* in most countries which contribute to these debates, and because the influence of biosafety and biosecurity improvements around the globe. Nonetheless, overlooking it thus means that many educational initiatives are premised on the assumption that there is adequate coverage of biosafety and biosecurity procedures and enforcement, mediation with external regulations such as customs, the presence of whistleblowing channels, and infrastructure to support new technologies and practices.

It is important to question exactly what implications de-emphasising the regulatory-physical environment in favour of internationalization and the promotion of role responsibilities may have on the ethical development of scientists around the globe. In particular, it is important to consider the following points:

- Could a lack of attention to the regulatory-physical environment also result in implicit assumptions being made in dual-use discussions regarding the level of coherence of the regulatory-physical environments? In particular, one must question whether current dual-use discussions automatically assume that all regulatory-physical environments are equitable to those occurring in developed countries?
- Could developing role responsibilities for dual-use control, in line with current trends in research ethics, lead to ethical confusion if they are transplanted out of the particular environment into situations where the regulatory-physical environment prohibits the scientists from fulfilling these responsibilities?
- Could this ethical confusion lead to cases where the concept of dual-use is rejected? Could this be rectified by explicitly addressing the influence of the regulatory-physical environment in dual-use discussions?

Such questions are difficult to answer without explicitly engaging with the regulatory-physical environments of laboratories. In this way, the fieldwork – in

particular the embedded observations that I conducted at each site – proved invaluable in interrogating these issues. In order to introduce the fieldwork findings coherently, however, it is important to first introduce some general observations about issues with the regulatory-physical environments of African laboratories that contrasts them from those in developed countries.

# 5.3 Accessing the Regulatory-Physical Research Environments at the Fieldsites

These initial observations regarding the importance of considering the regulatory-physical environment in ethical discussions involving developing countries correlate with my own experiences as a life science researcher in South Africa. At a number of times during my cell biology research I was confronted by a situation in which the behaviour expected of me (via university regulations, publishing standards or international science standards) was either impossible or pointless. Impossible, for example, when a paper that I was publishing was required to have a number of ethical checks that my institutional REC was unable to provide. Pointless, for example, when I was required to dispose of certain waste products in a certain fashion despite being aware that most other members of my laboratory poured the waste down the sink due to a lack of dedicated disposal facilities. In these and other cases, the inability to carry out the behaviour that was expected from me led to some serious ethical distress and "soul searching". However, it was equally likely that these experiences could have led me to reject these behavioural standards and to work in a manner that would have been deemed "unethical" by the international science community - for indeed, who was really to know?

Nonetheless, South Africa remains the most advanced country for scientific research in Africa - which raises considerable questions about the experiences of researchers in the rest of the continent. It has often been noted that African scientific research continues to be confronted with the challenges of poor research environments; inadequate manpower; inadequate infrastructures and

facilities; inaccessibility to modern technology; and lack of funds (WHO/AFRO 1998, Kirigia 2005). Indeed, as a recent Nature editorial stated that: *"it is easy to be fatalistic about science in sub-Saharan Africa. Researchers there face so many systemic problems – poor facilities, lack of funding, corruption and government instability – that it seems impossible for any single willing scientist in the developed world to make a difference for their African counterparts"* (Editorial 2011).

Despite the rather a bleak picture of the state of African science that this statement portrays, it strikes right at the heart of the problems plaguing research in the region. These include the absence of a wide enough knowledge base to sustain research and funding, and the absence of governmental support for many research initiatives (Steyn 2008: 26). In addition, poor research environments, inadequate infrastructures and facilities and the lack of access to modern technologies considerably affect these research systems (WHO/AFRO 1998, Kirigia 2005).

These concerns led me to seriously question how dual-use as a concept would be taken up by scientists in Africa, particularly as many of the discussions of controls and regulatory reforms would be seriously at odds with most research environments. Would the idea of increased regulations (or indeed any experiences had with the ones gradually emerging) send scientists into an "ethical tailspin" which could be traced back not to ethical dilemmas but problems within the regulatory-physical environment (in a similar fashion to Chambliss)?

In attempting to answer such questions it was obviously of considerable importance to get both participants' perceptions and interpretations of their environments while also gaining a clear and comprehensive understanding of the regulatory-physical environments of the fieldsites. To this end, the time spent conducting embedded research proved invaluable. The observations for this chapter differed from many of the traditional embedded sociology of science studies (such as Latour, Traweek and so forth), in that the focus was less on how the participants interacted together and more concerned with how they interacted with their environments – and indeed what the research environment was comprised of. Thus, understanding what research was being conducted, how it was being done, what equipment was available, how maintenance was carried out, what laboratory duties were required of the scientists, and how (paying homage to the OSM) the inputs and outputs of the laboratory were mediated were all given significant amounts of attention. My approach has previously been detailed in chapter three, which also contains the overview descriptions of each research site as a means of orienting the reader for the fieldwork portion of this chapter.

In my analysis of the field data it was gratifying to observe that many of the physical issues that I had highlighted during my observations were in fact the elements of the environment which were specifically alluded to by the participants. Furthermore, many of the regulatory processes that, from both the literature and my discussions with participants, I had identified as problematic were indeed those that were repeatedly referred to in interviews and focus groups.

In contrast to the previous chapter, different issues were raised in the various fieldsites. This was, of course, not unexpected due to the variations between the regulatory-physical environments between the fieldsites. This presented challenges for analysis, and led me to decide to present the findings as "vignettes" of situations illustrating the theme of the chapter, instead of a broader attempt at site descriptions in full. Nonetheless, it is my opinion that these isolated incidences all contribute towards a coherent larger picture.

The interview data presented below was mainly gathered during discussions during interviews and focus groups which centred on the possibility of controlling the dual-use potential of the life sciences, the "web of prevention" model, and the emerging strengthening of biosafety and biosecurity regulations around the world. Thus, the vignettes present a specific fieldsite's interpretation of potential problems that would potentially arise from introducing dual-use controls in their own specific research environment. These vignettes elaborate on how participants used a variety of environmental issues, such as lack of extra-laboratory infrastructure, lack of regulation, problems with equipment and absence of funding, as a means of expressing their disapprobation for dual-use controls. These discussions, as will be elaborated on below, also subsequently led to discussions on the role responsibilities for scientists commonly proposed by dual-use educational modules, and how these responsibilities were often not perceived to be in line with the capabilities of the African scientists.

Through the embedded observations I was able to isolate a number of issues relating to the regulatory-physical environment that served as themes for my analysis of the interview and focus group data. Each theme forms the headings for the sections that present the fieldwork data.

### 5.4 **Problems With the Extra-Laboratory Infrastructure**

As an open system, scientific research relies heavily on processes that both mediate the input of materials and data as well as those dealing with the outputs – both of data and of waste products. In most developed countries these processes are highly regulated and controlled. Such control is usually a combination of institutional regulations and national legislation. Crucially, it involves a combination of public and private partners and extends beyond the borders of scientific research. As suggested by my own personal experiences, and references from the literature (such as Kirigia 2005), the integrity of such systems cannot be assumed in many developing countries. In this section two different problems are discussed - that of waste disposal and that of corruption within society, and clarified as to their potential influence on ethical development.

## 5.4.1 <u>"I Know Something is Wrong, but I Can't do Anything About it": Waste</u> <u>Disposal Problems</u>

One of the fundamental aspects of biosafety in laboratory research is ensuring the correct disposal of the waste products generated during the course of research, something that requires input and coordination on national, institutional and individual levels. Many laboratories around the world utilize very similar waste disposal protocols, and the WHO manual on laboratory biosafety provides a good overview of these processes. In this manual, waste is defined broadly as "anything that is to be discarded", however this also includes the process of decontamination of wastes (WHO 2004: 17). In addition, dealing with waste also involves reusing and recycling large amount of glassware, instruments and laboratory clothing, as well as decontaminating, autoclaving or incinerating all infectious material within the laboratory (WHO, 2004: 17).

In order to safely dispose of waste materials, a system of waste separation is commonly used by laboratories. Using different coloured bags, waste is separated into non-contaminated (non-infectious waste) that can be disposed as household waste, contaminated (infectious) "sharps" (hypodermic needles, scalpels, knives, broken glass and sometimes pipette tips) which are collected in puncture-proof containers with fitted lids, contaminated materials for decontamination by autoclaving and thereafter washing and reuse or recycling, contaminated materials for autoclaving and disposal, and contaminated materials for direct incineration (WHO, 2004: 17).

Once the waste is correctly bagged and decontaminated within the laboratory, it is usually passed to an external company to dispose of correctly. "Sharps", for example, should not be discarded in landfills. Neither should contaminated materials destined for incineration – even after decontamination (WHO, 2004: 18). If the research facility is unable to incinerate its own waste, it is also

important that the incineration of contaminated waste must meet with public health and air pollution guidelines (WHO, 2004: 18).

Despite these clear guidelines, it has previously been observed that the disposal of laboratory waste in Africa is problematic. In 2008, for example, Katongole-Mbidde wrote that: *"[i]t is not uncommon, in developing countries, to see medical waste disposed of in a very unsatisfactory manner. Where attempts at incineration are made, one sees smoke in the sky because the technology used is inadequate. In some cases the waste and ashes are disposed of in a manner that allows the chemicals to seep into the ground and contaminate the water" (Katongole-Mbidde 2008). Such anecdotes are tragically common, and I personally have heard similar comments in the formal presentations and informal communications of participants at the African Biological Safety Association (AfBSA) and International Federation of Biosafety Associations (IFBA) conferences in 2010 and 2012.* 

Being in situations like these necessarily present problems for practicing scientists who, within the confines of the laboratory, are conforming to good biosafety practices. This is perhaps well illustrated by an observation from my field journal from the KY1 site:

"During the time I have spent in the laboratory I have carefully examined the waste disposal procedures. To my knowledge, within the laboratory they all seem correct and meticulously upheld. However, at lunch today I walked around the medical school and hospital grounds and observed that all the waste (red, yellow and black bags) was stacked together at the back of the building in an area open to the public. Furthermore, I saw these bags being loaded onto the back of an unmarked van together without separation. When I tried to follow the van, I saw the evidence that one or more of the bags had spilled, as there were syringes and tubes on the ground."

This rather cavalier attitude to waste disposal resonated with an earlier experience at other research site in the same country where I had observed similar practices. The issue of waste disposal (perhaps not unnaturally) came up repeatedly in the interviews at the KY1 site, with many comments such as the following: *"[h]ere I think it's fine, but if you go to the rural areas they get samples and if they can't process them they throw them away. ... Like here at [the medical school] they process samples and then throw them away. Maybe ... even throw in land or water, and that is dangerous" (KY1-5: MSc student).* 

Another participant in particular elaborated on issues relating to caveats in waste disposal protocols. An exert of the conversation included the following: *"P: Disposal is also a challenge. How do you dispose? You realize that no one cares. You can throw it in water, in the dustbin. Nobody cares. It is a problem and no one likes investing in that, but I think that is where biosafety affects people.* 

LB: That is a caveat in many grants – the funders assume that such issues like waste disposal are well defined and regulated.

*P*: Yes, it's a challenge. If you discover that things are not properly disposed of ... there is no credible company that will be 100% sure that what they've taken will be handled properly. They will give you paperwork and a certificate, but practically, you can't deny it happens. People don't know what to do with the waste. Someone has the contract but doesn't know what to do with the waste. It is general confusion all the way. I think that we don't have good disposal procedures. It can begin in a simple place like the lab, and go to industry. It's not about fear, it's about responsibility. Whatever you have, how can you dispose of it responsibly. Knowledge can be more powerful than law" (KY1-1: postdoc).

Thus, in many cases it appeared that despite observing waste disposal regulations in the laboratory, the scientists were aware that their compliance had little bearing on what ultimately happened to the waste. As was regularly mentioned in discussions, once the waste left the laboratory it was out of the

scientists' control and any changes in the system would be very difficult to affect. It was apparent that this situation was personally very concerning to all those who mentioned this subject.

A perpetuation of such a system, where well-intentioned regulations are being undermined by outside influences, appears to me to run the risk of spawning two different sets of problems. Firstly, by observing that their actions ultimately do not produce the desired effect scientists may become blasé about following regulations. Alternatively, it is possible that scientists, feeling morally obliged (or obligated by funding requirements) will take on the responsibility of ensuring that waste is correctly disposed of. Such responsibilities are far more than is expected from their Western counterparts, and it must be questioned whether it is fair to expect this from these scientists without making some provision for assistance (Bezuidenhout 2012).

As biosafety is an important element of the "web of prevention", and increasing biosafety regulations is a common topic in dual-use discussions, it is possible that the problems described above may significantly impact on the scientists' perceptions of dual-use. If, as I suggest, the current situation has the potential to seriously affect scientists' attitude to responsibility what, one might ask, would their reaction be to the proposed increases in biosafety regulations that dual-use advocates?

### 5.4.2 Evils That Lurk in the Deep: "The Curse of Corruption"

At the KY1 site, the discussions on export and import were regularly associated with concerns about corruption of national officials. Three participants directly linked the problems within the export and import system to corruption. One participant explicitly stated that: *"[t]he worst in our scenario [for export and import] is corruption. They may have the knowledge to do the right thing, but they turn a blind eye, because someone has corrupted the system. And then of* 

course there's a lack of knowledge. People handling the processes may not have adequate training" (KY1-2: technician). It appeared to me that many of the participants had this problem of corruption in mind when discussing customs issues, which led to an attitude that suggested that things were not really going to change much regardless of improved regulations and their best efforts.

Outside each building at the KY1 site there were signs proclaiming that "[The University] is a corruption-free zone". Indeed, when discussing corruption, all of the participants expressed pride at the integrity of the institution, and I heard no stories of corruption within that institute. Nonetheless, my own personal experiences at other institutions within that country, resonated with anecdotes offered by the participants and suggested that, unfortunately, corruption was rife in these academic institutions as well as in the government. One of the technicians elaborated on this situation in some detail, saying:

"Even now still the corruption is being fought, but other people do not understand this because it has become a way of life. Corruption is prevalent in all sectors. It is difficult to control information and research materials because of this corruption. Those who are corrupt do well, and if you aren't you don't. It's difficult to be a responsible scientist .. Some of this is inherent in an individual. Some people are corrupt, but there are some who try to live within the limits but don't do well. They end up not having a lavish lifestyle. It's tricky. Maybe Africa will have to start reinventing itself and not doing the things the way they have been. But as a scholar some of these things have been perpetuated by the West. They turn a blind eye. An example, look at Egypt – it was an ally of the US – that happens in institutions too. People they want to be involved with. They think they are good people. The kind of funding they get, whether they use it appropriately or not, they don't worry as long as they get their samples. So I think the West keeps playing the blame game, but we play things as they are. It's everyone's problem. More Africans need to understand that without their effort we won't come out of it" (KY1-2: technician).

This frustration with corruption was observed to directly affect how scientist viewed the addition of extra controls. Despite a strong national and institutional pride in their research and a desire to become more autonomous from their funders, all of the participants expressed hesitation at the idea of the national government being given charge of regulating scientific research. As one participant said: *"[y]es, there should be an international body that is set in Kenya to regulate what scientists do. Because Kenyans themselves cannot do anything. Most people are corrupt and they will abuse that body if it is set by the Kenyans. There should be a body, but an international one"* (KY1-6: MSc student).

In addition to the problems associated with corruption, the inability of the government to respond timeously to the emerging issues in scientific research was also commented on. Participants often described the government as a dense bureaucratic system of government that was not able to address the needs of the scientists. "One of the major challenges of doing research in Kenya is the bureaucracy of the policy makers. For you to get some stuff in to the country you need to have a license from the ministry of health, and they take long before you get anything. They are inefficient ... because you might think it's an urgent thing to do, but for them it's not an they take their sweet time. By the time you get your permit you've lost lots of time" (KY1-3: technician).

Time and again, there was a sense that the scientists were sceptical about whose interest the government and its officials had at heart. As another participant put it: "When you look at the level of involvement of people in the government. The people who are elected into these positions because they have big names or fat wallets and sometimes have no calling into the engagement that they are sitting for. This has killed our other institutions because of political interference. Lack of awareness and ignorance. That makes things not work in favour of the core process. We still have a long way to develop our system. The same thing that goes on in our political arena is the same that goes on in our other institutions. Same in the church, same in our *learning institutions, there is not democracy and people are not informed properly. There is another element of greed that I see. People want to remain at the top at all costs. Whether they are doing it wrong they don't care"* (KY1-2: technician).

The problems of corruption were known to significantly affect many areas of governance in Kenya. The widespread nature of this problem definitely affected the manner in which scientists at this site discussed possible regulatory measures. As evidenced above, the idea of increased governmental control over science in a combination with institutional controls, as proposed by Miller and Selgelid (Miller 2007) - was seen as extremely problematic<sup>105</sup>. How responsibilities for dual-use issues should be distributed in scenarios in which there is little faith in the government is an area of dual-use regulation that has, to my knowledge, not been discussed, but will prove extremely pertinent to future discussions on individual and collective responsibility.

The reaction of scientists in Kenya and Uganda to the idea of increased governmental control for scientific research also appeared to me to have a corollary: that they seemed less critical of the idea of international or by Western regulation. This lack of belief in their own regulations, combined with a slightly biased view towards the West has the potential to further skew the power balance as Africa struggles to find its voice in dual-use debates.

As one of the primary areas of responsibility for scientists designated in the "web of prevention" model is to uphold national and international biosafety and biosecurity regulations, and to promote national measures to deal with biorisk and dual-use issues. From the fieldwork discussed above, it would appear that upholding such responsibilities in the manner generally expected by the current dual-use debate cannot be assumed in developing countries. Indeed, better

<sup>&</sup>lt;sup>105</sup> There was a similar reaction against governmental control in Uganda. Although corruption was hinted at as a reason, most participants discussed an *"inability of the government to change"* (UG1-3: technician). As the president, Museveni, has been in power since 1986, this is perhaps not a surprising comment.

support for the difficulties experienced by scientists in these environments, and the inclusion of this sensitivity into discussions on role responsibilities may serve as a valuable means of engaging scientists in these debates.

## 5.5 Discordant or Absent Regulation

As mentioned above, an important element of scientists' responsibilities within the web of prevention is to uphold biosafety and biosecurity regulations. In addition to the problems described above, this raises another consideration: what happens if the countries lack functional biosafety and biosecurity regulatory systems? What implications could this have on the scientists' perceptions their of responsibilities?

With regards to biosafety regulations, it has been observed most countries in Africa continue to lack functional biosafety systems. Indeed, of the three African countries visited only South Africa is considered to have a functional biosafety system according to international standards (Sengooba 2008). Furthermore, it must be noted that the majority of biosafety discussions tend to focus on agricultural research and the issue of genetic modification (GM) in crops<sup>106</sup>, and not on the laboratory safety in the strict sense. This is reflected in the recent development of the African Model Law on Biosafety by the African Union (1999), which is primarily concerned with improving and sustaining food production in this region (Swanby 2009).

Although incidents involving biosecurity, as the intentional removal (theft) of biological materials from research laboratories, have not been common in Africa, there has been a growing focus on the need for African countries to

<sup>&</sup>lt;sup>106</sup> This, as discussed above, tends to contrast with non-African countries who "place greater focus on the threat of deliberately caused disease from hostile use of biological agents in biowarfare and bioterrorism and the possible future misuse of the results of benignly-intended research in the biotechnology revolution". UNAS (2008). Promoting Biosafety and Biosecurity within the Life Sciences: an International Workshop in East Africa. Kampala, Uganda, Uganda National Academy of Sciences.

either enhance their existing regulations or to create new ones governing laboratory security to prevent such occurrences (UNAS 2008: 8). The Kampala Compact (2005) and the Nairobi Announcement (2007) both recognize the need for African science to consider the threat of biosecurity relating to the use of dangerous pathogens and toxins for malicious use. Indeed, as most African countries are signatories of the BTWC, this obligation would appear almost mandatory.

Nonetheless, how this focus is translated into practical initiatives is by no means clear. As noted by Gorman: "[t]he seemingly distant connection between the governance of basic laboratory facilities needed for healthcare and the global reach of bioterrorism was recently recognized in the Kampala Compact. The compact stated that it is illegitimate to address the threat of bioweapons without addressing the enormous health crisis facing developing countries" (Gorman 2006: 56).

Thus, African countries face the twin challenge of developing biosafety and biosecurity regulations without unnecessarily burdening their emerging scientific research culture. Particularly relating to dual-use and biosecurity it must be noted that all three of the countries that I visited during the fieldwork were signatories of the BTWC, it was my understanding that biosecurity regulations in these countries were still rather poorly developed in comparison to those in developed countries. Indeed, there was little evidence at any of the fieldsites of institutional or governmental dual-use regulations.

## 5.5.1 <u>"We Can't Possibly Do That, So Why Bother?" - Improving Biosecurity</u> <u>Control</u>

During three interviews at the UG1 site I was told a similar story about a tuberculosis (TB, a BSL3 pathogen) reference laboratory which was based in same town as my fieldsite. As the quote below describes, this laboratory

appeared to have had less-than-ideal storage facilities for their samples, which could have led to not only biosafety but also biosecurity issues.

"P: I wanted to comment on biosecurity. In the other labs in [this town], if you take an example of the [the TB reference] lab, they take samples of all the strains circulating and there were drug-resistant strains. And these samples just lie anywhere, and anyone can just go and pick a sample and there is no control. Someone could just go in and decide to release them. In one place the freezer is actually outside. There is no lock or anything. It would just take someone to know which patient they were looking for and go and pick from the box.

*P:* People don't realize that poor sample storage is a security as well as a safety hazard.

LB: With the freezers being outside, do you think that was because of a lack of space, or a lack of awareness?

*P:* Space, but also because the lab has been managed by someone who didn't know. They changed to someone who was educated in Case Western [University in the USA], but he still didn't have funds. It's recently that he's got money from CDC – CDC and UNAID try to keep the lab going. The government doesn't really pay" (UG1-1: PhD student).

While this story was obviously not confirmable for me<sup>107</sup>, the unprompted relating of the same story by two other participants suggested that it was if not truth in entirety, at least something that the scientists were concerned about. Nonetheless, despite their concerns, all three participants, however, agreed that the lab was probably *"doing the best they can"*. Furthermore, without specific government input of funding and regulations, the scientists considered that the situation was at present unchangeable. However, they all agreed that *"the show must go on"*, as is obvious, the laboratory served an important purpose in the provision of healthcare to the country.

<sup>&</sup>lt;sup>107</sup> I had no access to the other laboratories in the town, and it would have been considerably difficult to gain access to a reference laboratory.

In contrast to the situation described above, international biosecurity guidelines detail a variety of equipment to restrict access and monitor a facility in order to detect unauthorized access. These include components for access control (laboratory perimeter; locks, keypads and electronic card readers; biometric scanners; visual identification badges; guards; and facility design) as well as surveillance (CCTV; infrared cameras; motion detectors; sound recording devices; and guards) (Clevestig 2009). In the case of a BSL3 pathogen such as tuberculosis, a high level of restriction is advised for physical security (Clevestig, 2009: 10).

In most developed countries, institutions receive "core funding" from governments, which cover general running costs including elements of biosecurity management. This money is then combined with competitive grants which are won by individuals or groups on the basis of scientific excellence (Olsson 2009). In contrast, tax revenues rarely form a significant element of research funding in developing countries (WHO/AFRO 1998)<sup>108</sup>. This longstanding failure of virtually all African governments to provide serious and sustained financing for research and graduate education has had a particularly deleterious impact on African research<sup>109</sup>. Thus, as is probably the case with the laboratory under discussion, lapses in biosecurity are not solely due to lack of education, but also because of lack of funding to uphold the expectations placed on the facility.

<sup>&</sup>lt;sup>108</sup> South African government makes the highest contribution towards higher education at 1% of national budget for education Dibetle, M., Mohlala, T. (2010). Budget snubs academics. <u>Mail and Guardian</u> Johannesburg, Anastacia Martin. **22/02/2010**.

<sup>&</sup>lt;sup>109</sup> For example, "[*i*]*n* 2006, Uganda won \$30 million in low-interest loans through the World Bank's Millennium Science Initiative, and has used that windfall to fund research grants. With the money running out, the country declined an opportunity to seek more loans, and promised to support the research projects on its own. But Uganda's latest budget did not include such funding" Editorial (2011). "A helping hand." <u>Nature</u> **474**: 542.

The awareness of this dichotomy between the "ideal" and the "real" biosecurity procedures was something that has been commented on regularly during the fieldwork, and also in conversations that I have had with other African scientists at conferences and socially. Notwithstanding the issues regarding dual-use ownership discussed in the last chapter, most of the scientists I talked to indicated that they would have been happy to improve security in their facilities. However, comments such as *"we'd like to do that, but we don't have the money"*, and *"we're doing the best we can with the facilities we've got available"* regularly made appearances in these discussions.

This dichotomy between the internationally sanctioned "ideal" state of biosecurity and the "on the ground" initiatives able to be put into place in African laboratories places scientists in a potentially ethically compromising position. While of course most scientists recognize the importance of security in a research environment, the twin challenges of lack of core funding and lack of coherent government regulations makes implementing biosecurity measures difficult. Nonetheless, especially in the case of reference laboratories such as the TB one described above, the research being conducted in these facilities is of vital importance and, as it were, *"the show must go on"*.

It is possible that these issues may manifest themselves as two important problems for dual-use discussions. Firstly, as with the waste disposal problems discussed above, the dichotomy between the "real" and the "ideal" may undermine researchers faith in security requirements – a situation no doubt complicated by the relative lack of buy-in regarding bioterrorism, as discussed in chapter four.

Secondly, the inability to meet security requirements was often perceived as possibly having significantly detrimental effects on future funding and collaboration opportunities, as security becomes increasingly prioritized by the
international science community<sup>110</sup>. Thus, it appeared that they were unwilling to discuss shortcomings in their laboratory and national security arrangements for fear of jeopardising future funding possibilities – something that would significantly detract from a proper representation of African concerns in international dual-use discussions.

## 5.5.2 <u>"They're Not Our Issues, Why Should They Be Our Problems?": Export</u> and Import

Another important element of the "web of prevention" model is the strengthening of export and import controls on national and international levels. The increasingly international nature of life science research means that adequate processes for importing and exporting samples, reagents and equipment are vital to the success of any research endeavour. Professional handling is vital for most long distance transfers where the sender cannot personally supervise the transfer of the materials, and in most developed countries certification is needed to ensure that the shipping company has a valid license for handling dangerous goods.

In recent years, the transport of dangerous pathogens and toxins across borders has become an area of considerable international concern, and many countries have developed national guidelines to deal with these issues. Furthermore, these concerns have led to considerable support for the development of international guidelines which are based on the UN regulations for the two most hazardous categories of materials (A and B) (Clevestig 2009: 12). Many countries regulate the export of biological materials, equipment and technology as part of their effort to prevent the proliferation of weapons of mass destruction, including biological weapons (Clevestig, 2009: 14), and indeed a number of countries have recently passed legislation to combat terrorism that introduces new criminal offences relating to export (Clevestig, 2009: 14).

<sup>&</sup>lt;sup>110</sup> I also noticed this perception in my conversations with conference delegates at the International Federation of Biosafety Associations (IFBA) and African Biological Safety Associations (AfBSA) conferences that I went to.

African countries have not been as involved in this international climate of heightened security (UNAS 2008: 8), and the development of stricter border security remains (in many cases) a work in progress. Nonetheless, as import and export of materials involve inter-national regulations, African border controls are increasingly being confronted with the heightened security regulations from developed countries. Issues relating to import and export, especially in the post-2001 research environment, came up in nearly all the interviews and all focus groups at the four African fieldsites. Many interviewees related personal experiences with border control issues, such as the following exchange:

"P: Getting stuff through customs and shipping has been difficult on occasion. Recently one company, "dangerous goods international" just refuses to ship DNA – doesn't matter what it is – they want a whole lot of supporting documentations like MSDSs [material safety data sheet], but you don't get MSDSs for plasmids. So that's been a bit difficult. And then we imported a lipid and it took us almost two months to get it out of customs. They wanted more and more information. And the system for getting things in the country ... and there are no documents explaining things to the lay person who's not involved in import export, so you go to the customs clearing house and they say that you're not an agent so you can't take it out – even if you pay the duties.

LB: So the customs officials are following the rules to the letter ...

P: ... even if they don't know what they're about. And recently you're not allowed to ship dry ice, even if you want to ship cells that you want to send overseas then you have to find another way. You have to revive them and hope that they survive the trip." (SA2-1: PhD student).

This quote raises two important points that were repeatedly mentioned by participants in all four African fieldsites. Firstly, as discussed in the quote, that there are difficulties arising from not being able to produce the documentation

that is required by foreign companies and research facilities which present a considerable challenge to researchers. This difficulty, as discussed above, was also touched on by researchers and lab managers at the UK site, however in such cases clear attempts were made to resolve these systemic issues by the university and government.

The second problematic area highlighted in the quote relates to the difficulties arising from poorly briefed customs staff. The difficulties of getting reagents and samples through customs was a regular complaint in all the labs, and statements such as: "*[i]f you need to order a restriction enzyme that you need to use urgently, it can take six weeks … it really is an impediment to progress*" (SA2-5: HoD) resonated with my personal experiences of working as a scientist in an African country. Another participant at another site elaborated on the problem, suggesting that: "*[t]he huge problem is that they [the customs officials] see something and don't understand what it is, and keep it at customs for months. So that's … and we always wonder why we wait so long. And a lot of the companies don't have reps here, but have little independent companies that represent them, so that's another problem. We're going from dealing with the company to third party really" (SA1-7: PhD student)* 

Indeed, most of the participants mentioned that any international attempts to improved export and import on a global level would hinder, rather than help, their attempts to carry out research. Increasing international regulations without adequately training national customs officials and harmonizing national regulations, it is easy to see, would no doubt exacerbate the problems discussed above. As one PhD student succinctly put it: *[i]t already takes four to six weeks to get a delivery through, so any extra restrictions will make it even worse*" (SA2-1: PhD student).

The recognition of the possible (indeed, probable) complications in export and import that would result from improved international dual-use regulations often led to the African participants responding to my questions on the subject with sighs, shrugs, and eye rolling. In addition, however, some participants in the SA1 and KY1 sites mentioned anecdotes in which scientists circumvented legal customs procedures in order to avoid the bureaucracy surrounding sample transport<sup>111</sup>. One participant at the KY1 site succinctly summarised this as: *"[p]roblems are diverse .. in our scenario they don't do what they are supposed to do. Over time you find people walking in and carrying away tissues and no one raises a concern"* (KY1-2: technician).

It was interesting to note that when I was told these stories the participants, while acknowledging that the behaviour of the protagonist was wrong, expressed sympathy for them and believed that that they were acting with "beneficial intentions" at heart. It appeared that they viewed the need to conduct research as more important than dealing with a bureaucracy that was obtuse, poorly regulated and non-reflective of the needs of the science population.

Poorly harmonized and executed customs regulations thus place scientists in an impossible situation where their research is slowed down (sometimes indefinitely) by an increasingly dense mélange of security requirements. In such cases could it be understandable that scientists are tempted to conduct a "risk/benefit" analysis of the possibility of circumventing the system and advancing their (beneficial) research (Bezuidenhout 2012)?

If scientists do choose to uphold the regulations, their poor execution runs a serious risk of breeding contempt instead of endorsement amongst the science population. In such cases, it must be seriously questioned whether the heightened regulations resulting from dual-use awareness will serve to bring African scientists round to the cause, or further alienate them instead.

<sup>&</sup>lt;sup>111</sup> These anecdotes were related to me in confidence and are therefore not to be quoted. Nonetheless, they allowed me to build up a good understanding of what scientists would do to avoid complications in export and import.

## 5.6 **Problems With the Physical Infrastructure**

As discussed above, one of the mute points of the dual-use dialogue are the assumptions made regarding the infrastructure supporting scientific research. While the presence of adequate electricity, internet, and technical expertise may rightly be assumed to be sufficient in developed country settings, my experiences (both as a practicing scientist and as a visiting researcher) strongly indicate the contrary in many African laboratories. Thus, as was often the case, discussions about increased biosafety and biosecurity controls were met with (justified) scepticism – as the scientists were already struggling to maintain their daily standards.

### 5.6.1 <u>"We Can't Work Without Power!"</u>

The problem of adequate electricity supply was something that I personally encountered in the course of my time in a South African laboratory, and which complicated the daily process of research to no end. During this research similar problems were encountered at the KY1 site. The extract below is taken from my field diary on the third day after starting research there.

"Day 3: Today I woke up to find that the power-substation in [the district in which the medical school was based] had burnt down. I found out that it was in the middle of a squatter [informal settlement] camp and a large fire had resulted in considerable damage to many buildings including the power station. There is no power in the entire district. When I arrived at the lab I found that it too was without most of the power, as the emergency generators were unable to cope with all the lab power needs. I found out that [the laboratory manager] and [two of the technicians] had been in since daybreak moving samples onto ice and into other freezers. No work can be done, as none of the hoods and centrifuges are able to operate on the emergency power supply." This fire and damage to the substation subsequently caused over three weeks of irregular power supplies. In the first week there was very little power at all, and after that there were periods of between one and five hours of no power. This had a considerable effect on the medical school, as their emergency generators struggled to keep up with the power requirements. Within the department 28 different units were connected to the emergency power supply, including the pharmacy. In order to maximize the power, there was considerable reshuffling of samples and rescheduling of work plans.

While the lab staff were frustrated by the disruptions to their work, they appeared resigned to these problems. In many cases the lack of power worked in my favour as the staff were able to spend extended periods of time talking to me – something they would no doubt not have been able to do with their former work schedule. During these talks, however, the contrast between the problems that I wanted to discuss and the very obvious immediate issues they were dealing with was often highlighted. Indeed, my requests to discuss possible dual-use controls were often met with wry smiles and humorous comments on being "in the dark". This got me to questioning how exactly dual-use and ethics education could be made pertinent in the face of such overwhelming logistical problems.

#### 5.6.2 <u>"We Have the Machines, but We Have No One to Fix Them"</u>

South Africa is in a privileged position compared to the rest of Sub-Saharan Africa as it has the most advanced research community, and is a hub for the distribution of materials and expertise to the rest of the region. This means that in most cases qualified expertise can be sourced to deal with technical issues.

In Uganda and Kenya, however, this is not the case and the difficulty of maintaining the expensive equipment purchased from grants was a topic which came up both at lab meetings and in discussions with the laboratory managers.

During the lab meeting at the UG1 site there was an extensive discussion on the possible need to start self-servicing the Gilson pipettes due to the time and cost of sending them away to be calibrated. I have never been exposed to such discussions before (although I was aware it was possible, self-servicing something as sensitive and crucial as pipettes is not something many scientists would choose), and forced me to question whether the lists of duties ascribed to scientists in different research environments might differ so much as to warrant closer inspection – particularly the way that scientists view their responsibilities. If students, scientists and technicians are taking on a host of duties which, in developed countries, are normally sub-contracted to qualified and regulated businesses it may be that the distribution of responsibilities in the "web of prevention" rhetoric needs to be re-examined.

Furthermore, the laboratory managers in both the UG1 and KY1 sites mention the difficulty of finding qualified servicing engineers for lab equipment. The lab manager at the KY1 site explained this difficultly in detail, saying: *"[o]ne of the major impediments that we had when we began was biomedical engineers. The government has courses, but the equipment requires well-trained individuals.* That was a problem. After discussion with IAVI we identified a company in Europe and asked them to open an office in Nairobi. Now they can help other labs in Africa and India, so that was resolved" (KY1-7: lab manager). This topic suggests that there is a strong need to view scientific research in a broader scope – and that discussions cannot start and stop with the laboratory, but need to include the support systems which need to be in place to make research feasible. Without doing so, funding, ethics and empowerment become rather null and void.

The following quote was taken from a discussion with a PhD student. We were talking about the possibility of utilizing kits for research made in Africa<sup>112</sup>. His response, I think, is pertinent to this discussion and focused not on the *expertise* needed to produce the kits, but on the *systems* needed for kit

<sup>&</sup>lt;sup>112</sup> South Africa has a small, but increasing, scientific reagents industry and also produced diagnostic tests. Furthermore, KEMRI in Kenya has recently started producing a small number of diagnostic tests commercially.

production that might be at fault in an African setting. He said: *"[a]ctually, Africa can provide cheap labour for producing these kits. I think Germany, most of these kits we use come from there, they cost more being produced there as here. But actually Africa has its own problems – there's no electricity, there's dirty water, I mean .. (laughs)"* (UG1-1: PhD student). Thus, without the support systems needed – including qualified engineers – it is unlikely that African scientists will start supporting commercial endeavours, or indeed give African science the credit it deserves.

Both of these issues suggest an important caveat in most practical and ethical discussions regarding science in Africa: that the basis of support for scientific research needs to be actively stimulated and supported. Furthermore, that it is insufficient to consider any support as ending at the walls of the laboratories, but rather it needs to extend into the broader community of technical support structures. Only by building capacity in this area will scientists in Africa start to believe in the capabilities of their fellow countrymen and start to make use of the services that are offered. This observation has important implications for dual-use discussions, as without the mutual support and development of both the scientific research population and the associated businesses that support research any "web of prevention" is considerably weakened.

#### 5.6.3 <u>"What's the Point of Open Access if You Don't Have Internet?"</u>

A recent paper observed that: "low computer literacy hampers the current trend of delivering lecture materials in e-mode, as well as limited access to computers and the level of available internet connectivity and wireless technology for free access to services based on these technologies" (Kenya 2008). Indeed, my time in Kenya emphasized how few computers were available for use by the staff. Indeed, even the records from the clinical trials were filled in by hand and stored as physical copies in large files. Similarly, while staying at the UG1 site (I was living on-site) I was unable to utilize the internet for most of my stay. Indeed my experiences, as confirmed by participants, were apparently not out of the ordinary. Problematic access to internet, slow download speeds, and limited access to online materials continue to be significant problems for African scientists. In particular, the related problems of limited access to journals and e-resources came up regularly in discussions (even in South Africa), and many participants rated that as one of their primary difficulties in daily research. As one participant mentioned: *"[j]a, access to articles is a problem – for example at the moment the Journal of Infectious Diseases is not open. The articles that I attempt to get, these are not freely accessible and I had to write to people to get them to send them"* (UG1-1: PhD student).

Within dual-use discussions, considerable emphasis has been placed on the use of online tools to educate scientists and raise awareness. Although recently there has been some mention of the limits of this approach in developing countries (NRC 2011), less attention has been paid to developing alternate modalities that sidestep the need for online access. Often, problems associated with access to information, download speeds, online streaming and other problems relating to online education and research require considerable further investigations.

These three sets of observations all raise important considerations for ethical discussions about dual-use. Firstly, if scientists in developing countries are often struggling with fundamental issues such as the provision of power and water in their daily research lives, how concerned can anyone feasibly expect them to be about dual-use issues? Is it not important that these extreme variations in daily research practices and pressures be reflected not only in the educational materials, but also in the funding opportunities – where core funding might be dedicated to alleviating these issues. Particularly relating to dual-use education, how could existing courses be adapted to have greater sensitivity to these basic contextual variations?

Furthermore, and particularly in terms of increasing capacity for dual-use issues around the globe, it is vital that the dual-use community recognise the limitations of many research environments when designing educational modalities. Although an online case study repository may be of considerable use to some scientific communities, for others it is largely an inaccessible resource. Thus, assuming that information will be accessed simply because it is online cannot be taken as a given when designing educational modules.

# 5.7 Building Regulatory-Physical Environments: Finding Funding

The issue of funding, and the difficulties associated with it came up in every single interview and focus group conducted in Africa. These issues usually fell into a number of different groups: the lack of, or difficulties with, government funding; obligations associated with international funding; and the lack of funding for basic research (as opposed to applied sciences or focused research projects).

Both the KY1 and UG1 sites suffered from a lack of government core funding for their facilities - indeed, the UG1 did not receive any funding from the government at all. This was observed to create considerable problems for the scientists working in these facilities, and I was told resulted in strictly limited possibilities for doing independent, basic research. Furthermore, as so much of the funding for these institutions was tied to specific projects, any disruption in these projects had considerable consequences. For instance, during a lab meeting at the UG1 site it was mentioned that a number of projects funded by the overseas donor were ending. Because of this there was a potential need to either downsize the unit and fire staff, or to move the staff onto other projects. This was observed to place considerable strain on the working conditions. The lack of government funding for research was definitely an issue of considerable discontent at both sites. As one participant in Kenya mentioned: "It's the responsibility of the government to fund basic research. I don't know what could be done to get the government to fund the basic research ... our government would rather the donors come in and do the clinical research and not put in any money themselves" (KY1-3: technician). Similarly in Uganda, participants highlighted the lack of government support, saying: "I don't like the structure of work here, actually I hate it, but we won't transform Uganda by running away. We have to confront it. Some of these problems in the country we will get over as the country goes forward ... but the government needs to put money into research. We still rely on Wellcome Trust, NIH, CDC and so forth and they are the ones that fund the studies in Africa. The African governments aren't funding – apart from perhaps South Africa, and one percent of the GDP is better than in Uganda where even the government doesn't buy its own drugs for the patients – they rely on the CDC. We are government [a government institute] I think, but most of our staff is paid by CDC or MRC or IAVI or WHO, so we really have very little government input within the research. For example, we recently had an outbreak of yellow fever. The government said that they didn't have money to buy vaccines for these guys. And this is a government who says it is important to buy vaccines. They say that they are trying to give more scholarships to people to go to the university to study science, but they haven't come up with a plan of when they leave their bachelors what do they do? When they leave their masters what do they do? When they have a PhD where do they go? It's actually a big challenge" (UG1-1).

The issue of lack of government funding appeared to be compounded by the necessity of thus having to compete for international funding to conduct research. This was confirmed by the HoDs in both Kenya and Uganda, who made specific mention of the difficulties in applying for international grants.

"P: The other pressure is that the funding is never local. The funding is always international. It makes it difficult. With the international economy the way it is, countries are tending to look inwards and fund their own.

LB: Why doesn't the Kenyan government fund research?

*P:* Part of it is priorities. They don't see research to be of any benefit. They understand research, but don't see it as being of immediate benefit. Maybe it's also an issue of us scientists. We don't take time to explore ways in which we could be funded locally. So we are left with no choice but to compete internationally with organizations that regularly fund" (KY1-8: HoD).

The lack of core funding was also seen as having a stifling effect their ability to advance independent research. Over and over again, statements such as the following were made in which participants questioned how African research could be made sustainable without core funding.

"The problem is funding, especially from the government because of the constraint of resources. There's not enough funding. Those equipment are very expensive to purchase and maintain, so they need committed money and resources and sometimes the government doesn't have that capability. You wonder what's a priority. I believe even where we have the capacity to perform those techniques, the challenge is maintenance. If you come two or three years down the line will you find the same state-of-the-art facility without anything interfering? Not so" (KY1-1: postdoc).

Because of these trends in funding, many African research institutions struggle to drive their own research. Although international donors are gradually starting to realize that in addition to funding research projects they must also strengthen the administrative and leadership capacity of African research institutions (Nordling 2010), there is still a long way to go. This problem of a lack of governmental support for research has the potential to have severe consequences on the development of the dual-use debate in these countries. If, as is evident, scientists do not feel that the government has their interests at heart or values their research, it is possible that the development of governmental regulations to deal with dual-use issues may be met with hostility. Furthermore, the continued reliance on foreign funding makes it possible that African scientists do not feel that they have the autonomy and power to develop their own approaches to dual-use control and significantly contribute to the international debate.

## 5.8 Contributions of the Regulatory-Physical Environment To Ethical Development and Dual-Use Awareness

The fieldwork data presented above highlights some very interesting points for consideration, all of which related to the current perceptions of the role of scientists in dual-use prevention. As discussed above, a number of studies in dual-use ethics have identified some duties for scientists including preventing bioterrorism, engaging in response activities, limiting access to dangerous materials and reporting activities of concern (Ehni, 2008, Kuhlau, 2008), as well as those responsibilities associated with biorisk management. These different duties have come to be embodied in a number of role responsibilities expected of scientists as part of the "web of prevention" model. These could be taken to include surveillance of research for dual-use potential, raising awareness of possible concerns, upholding existing biorisk regulations and engaging in awareness-raising activities. These role responsibilities have come to play an important role in dual-use educational initiatives (NRC 2011).

When considering the field data it became apparent that these role responsibilities, and the behaviours they expect to elicit, have the potential to present considerable problems to scientists in developing countries – due to the under-discussed variations in the regulatory-physical environments and the contextual nature of these responsibilities. In particular, my observations and

discussions with the scientists about their research environments led me to identify four different ways in which it contributed to their perceptions of responsibility and ethical behaviour. These included being unable to fulfil certain prescribed duties (such as waste disposal), having conflicting responsibilities (such as those involved in export), having unrealistic responsibilities placed on difficult circumstances (such as being without power), or lacking control or support (such as lack of governmental funding). All of these observations, to my mind, significantly affected the ethical engagement of scientists with the dual-use concept and, if not addressed, would potentially seriously undermine the success of any educational initiative.

These problems make it important to reiterate the work of Daniel Chambliss discussed above. It would appear that many of these issues, which are identified as ethical problems by the scientists involved, are not ethical problems *as per say*, but rather issues relating to the systemic environment in which they are occurring. These issues could include disjunctions between systems, absence of certain systems, or different vested interests and priorities of the myriad of national, international, public and private partners in the research process be considered in some detail.

Nonetheless, a failure to address these issues both in educational initiatives and in policy, can result in a sense of moral dissociation for scientists as they are faced with seemingly unreasonable or unfeasible responsibilities. Thus, increasing regulations without significantly increasing the coherence of the systems in which thy are implemented can lead to a situation in which scientists viewed the regulations as both complicating their daily research and largely pointless.

It was interesting to note that even when participants were open to the idea of improving biorisk management and addressing the dual-use potential of research, they faced two obstacles. Firstly, there were considerable hesitations about regulations and requirements coming from foreign countries – particularly as there was a general perception that these would not be reflective (or sympathetic) to their situation "on the ground". Thus, one must question how (if at all) attitudes may be readjusted so that regulations are not viewed as "foreign impositions", but rather as an organic process of improving self-regulation.

Secondly, it was very apparent that even in South Africa (where the government did provide core funding to the institutions) that laboratory budgets often did not stretch to implementing some biosafety and biosecurity recommendations detailed in the WHO reports. It must therefore be asked whether, in the absence of dedicated funding for implementing these procedures, the entire process of "strengthening the web of prevention" thus becomes a pointless exercise in rhetoric instead of an actuality. Such cases will no doubt further serve to alienate scientists, as they become an exercise in absurdity.

The observations made above not only have significant repercussions for building and sustaining individual dual-use awareness, but also can be seen as influential to discussions regarding responsibility amongst scientists. Notably, most discussions on collective responsibility trade on a simplistic notion of an aggregation of individual responsibilities. Furthermore, these individual responsibilities were mediated by the model of distributed responsibility that the "web of prevention" promotes. This fieldwork shows that such an approach is problematic for two important reasons.

Firstly, it was very obvious from the fieldwork (particularly in Kenya and Uganda) that scientists lacked faith in their governments, regulatory systems, and private firms involved in scientific research (such as waste disposal companies). Thus, the model of distributed responsibility did not resonate with them. Indeed, the possibility of increasing governmental oversight for scientific research was often met with hesitation or scepticism. Thus, one must question whether promoting this approach to responsibility does not, in fact, detract from dual-use support instead of facilitating it.

Secondly, the fieldwork amply identifies the regulatory and physical challenges of conducting research in a developing country. Many of the participants expressed despair at the idea of new regulations or procedures becoming mandatory in environments in which they were already struggling to conduct research. Indeed, in situations in which internet, power, clean water and so forth are not guaranteed, their hesitations are understandable. Without clearly promoting a nuanced and contextual interpretation of the role responsibilities that would be expected of scientists in a specific regulatory-physical research environment it is likely that scientists will feel alienated or discriminated against. Furthermore, it is unlikely that, given their inability to meet certain standards, that they will identify with the idea of collective responsibility as an aggregate of individual efforts. Is such an approach actually driving scientists away from the idea of a *"shared sense of responsibility within the global community of life scientists"* (NSABB 2006) instead of fostering it?

### 5.9 Changing the Way Responsibilities are Presented?

A close examination of the regulatory-physical environment and its influence on ethical development raises two salient points for further consideration. Firstly, as role responsibilities are developed within a specific context, it is important that they be explicitly interrogated in relation to the regulatory-physical, as well as the social, environment for which they are developed. In particular, this is of vital importance for the propagation of broad social issues that are not united by the specific focus of research ethics (as discussed in chapter one). Thus, the ethical duties suggested in the existing literature on dual-use ethics needs to be carefully re-assessed in relation to the context that it is implicitly referring to, and not assume that these duties could be automatically transmissible between research cultures. This is of particular importance when one considers the possibility of ethical fatigue or dissociation that may arise if scientists are presented with role responsibilities that patently do not reflect the environment in which they work. Based on the speculation above it may be possible to suggest that scientific communities need greater freedom to develop a way of translating the global responsibility of dual-use into practical daily behaviours. By promoting "moral citizenship" and "professionalism" within educational modules, instead of focusing on role responsibilities and regulatory duties it may be possible to promote a "practical wisdom" amongst scientists so that they are better able to deal with the idiosyncrasies of their own particular regulatory-physical environments and the conflicting demands made on them. This proposal will be further examined in chapter seven.

A second consideration arising from the investigation of the regulatory-physical environments of scientific research is concerned with the notion of collective responsibility and the limitations of presenting it as an aggregate phenomenon (as discussed in chapters one and two). If, as was proposed by Miller, collective responsibility may be understood to *"mirror that of individual moral responsibility"* (Miller, forthcoming: 11. As discussed in 2.2.2), one must question exactly how this includes developing country scientists who cannot fulfil the requirements expected of them by developed countries. Does this inability make them immoral and exclude them from scientists as a collective?

Instead, as the fieldwork suggests, it may be useful to propose an alternative interpretation of collective responsibility that may more adequately reflect the Open System of scientific research and the high degree of variation present in the regulatory-physical research environments around the world. In doing this, it is helpful to consider the work of Larry May, and in particular his 1996 book *The Socially Responsive Self*.

In this book May re-examined professional ethics from a communitarian and collectivist perspective, thus presenting an innovative interpretation of current theories of collective responsibility. In his work, May questions what would be

necessary for individual professionals to live up to their moral commitments, while also standing up to possible negative pressures. Importantly, he emphasises that individuals are members of multiple groups and organisations which seek to impose different sets of values and claims for loyalties on their members. Thus, May asks, how is a shared sense of responsibility negotiated by an individual for membership in diverse groups?

In order to clarify his position, May proposed that individual responsibility viewed as a "web of commitments" to different groups, which presents multiple, perhaps even conflicting, commitments, not from the challenges of differing professional and personal identifies and even incompatible epistemic cultures and moral priorities (May 1996, Malsch 2009). Thus, through this "web of commitments" individuals make legitimate negotiated compromises, and it is vital that possible conflicts within these "webs" are made explicit to avoid ethical crises. May emphasises that these negotiated compromises depend not only on the personal integrity of the individual, but also on the solidarity and support of the groups and organisations. Thus, in order to expect individuals to obey the demands made of them, groups must offer support for them.

May's interpretation of collective responsibility thus offers a very different vision to the aggregate model currently employed in dual-use discussions. Importantly, it highlights not only that the responsibilities placed on individuals vary between contexts (thus eliminating the possibility of universalisable role responsibilities), but also that the priorities of individuals will change depending on the commitments it is party to. May's model, of course, requires considerable individual discourse and contextual analysis, but it is possible that when used in conjunction with the OSM a more inclusive approach to the "web of prevention" and dual-use controls could be developed which would resonate with scientific communities around the world.

It is important to note that in his work May emphasises the importance of solidarity within groups, which he takes as necessary to their moral authority.

This solidarity, he proposes, develops from individuals identifying with the group. Within the discussion of dual-use responsibility this is a key, yet often mute, point. Little attention is given to whether scientists identify with the greater science community, or whether they view themselves as "removed" or "apart" from the fold. In the fieldwork it was definitely apparent that the suggestion of rules that were insensitive to the particular areas of conflict within the fieldsites influenced the participants' perceptions of themselves as part of the international science community.

It must be noted that while these issues are less prominent in developed countries, they are also by no means totally absent. In a discussion with a research manager at the UK1 site I had the following interchange:

"P: Our funding comes from the NIH so yes, it [increased security awareness] does affect our funding. Regulations as well. We have to, in terms of transferring materials and clinical samples across. There's a lot of regulation that we have to cut through – American and British. And there's actually less regulation for that kind of work here than in the States. It's much more bureaucratic in the States.

LB: So do your regulations come from the Home Office?

*P:* no, um, with the human tissue samples we have something here called the Human Tissue Act, but that only covers samples collected in the UK and doesn't cover samples brought in from abroad, so you need to have that documentation to say that you have permission to do that, and it's actually really difficult to do that.

### LB: Who would you get it from then?

*P:* Now we've started being able to get it from the research office here, because if you go to the ethics committee and say that I need this approval, they say that they don't cover it, and that you don't need their approval. But I need something to show the Americans that we have approval to receive these samples" (UK1-9: research coordinator). This clearly demonstrates that disjunctions between different regulations or between regulations and the physical environment happen "across the board". Thus, changing the focus of discussions on collective responsibility will benefit all scientists, and allow them to clearly situate themselves within their personalised interpretation of the "web of prevention". Furthermore, by examining the various commitments that promote or hamper building dual-use awareness it is likely that future awareness-raising initiatives will be strengthened.

## 6 Perpetuating a Sense of Responsibility

Chapter four looked at how scientists engage with the concept of dual-use, and chapter five at how they related it to their daily research. This chapter, in contrast, looks at how dual-use awareness may be fostered and perpetuated within laboratory environments. This relates to the third concern regarding suitability of using RCR methodologies to teach broad social issues, and how effective they are in fostering ethical cultures of responsibility within laboratories.

As discussed previously, the RCR model significantly endorses the notion of "teaching through experience". Thus, within the RCR model, mentoring in daily research, and the emphasis on learning and reinforcing appropriate behaviours *in situ* play an important role in the perpetuation of research integrity. In the RCR model, mentoring is generally assumed to occur through a hierarchy of from the head of department (HoD) and principle investigators (PI), through the research scientists and postdoctoral scientists to the students and technicians (IoM 2002). Within this "chain of mentoring" (in the RCR model), the PI plays a fundamental role in ensuring that role responsibilities are adequately transmitted and implemented within their group (IoM, 2002), and that integrity is promoted in the research.

As the RCR model places a considerable emphasis on preventing misconduct in research, it is easy to see how "teaching through experience" plays a vital role. By continually monitoring behaviour or peers and subordinates, scientists are actively able to promote a culture of research integrity and good conduct. This supports current ethics education that relies on the lessons taught in the classroom to be reinforced by daily practice. Indeed, it may be said that "learning by experience" is as valuable for the ethical growth of a learner as the formal lessons themselves. Despite the emphasis on "teaching through experience" for the prevention of misconduct in scientific research, less comparatively has been said about how "good behaviour" (ie. beyond the absence of misconduct) is fostered and perpetuated in science. Because of this, discussions regarding teaching responsibility for broad social issues through daily experiences are extremely complicated. It is evident that avoiding misbehaviour is not sufficient, however how global responsibility can be fostered through daily practices is far from apparent.

In attempting to analyse this issue, it is helpful to borrow a concept from business ethics: that of "ethical cultures". This concept is explicitly concerned with how ethical behaviour can be viewed as much as a product of the environment in which it occurs, as due to individual inclination. Importantly, ethical cultures foster good practices in business as well as prevent misconduct. In this manner, discussing how "ethical cultures" can be perpetuated within laboratories becomes an important tool for perpetuating dual-use awareness.

The notion of "teaching by experience" through mentoring and supervision is already central to dual-use aspirations of building a "common culture of awareness and a shared sense of responsibility amongst the global life science community" (NSABB 2007: 5). Indeed, many dual-use educational initiatives, and models of control thus emphasise the importance of the PI and other mentors in transmitting and upholding the concept of dual-use awareness within their research groups. However, as this chapter observes, the notion of "fostering ethical cultures" in laboratories is rarely well discussed in dual-use educational initiatives. Instead, "teaching by experience" is often referred to obliquely, and little is said regarding how PIs should foster dual-use awareness within their laboratories.

Thus, it would appear that the notion of ethical cultures has not been properly unpacked in dual-use education, and often rely on RCR-related notions of "teaching through experience" when addressing this issue. Thus, in dual-use discussions, the perpetuation of ethical education and the transmission of information is assumed to be the responsibility of the PI, who in turn relies on a "chain of mentoring" to address his staff.

Nonetheless, as this chapter will suggest, such a situation is untenable. The RCR approach "teaching by example" to avoid misconduct, I suggest, cannot be equated to "building ethical cultures of dual-use awareness". Furthermore, a diverse range of issues from social traditions, lack of funding for permanent positions and rigid career hierarchies all force suggest that relying on Western interpretations of the social and hierarchical structures of laboratories is potentially damaging to building capacity.

These observations are clearly demonstrated in the fieldwork presented in this chapter, which shows that the social culture of laboratories – while remaining ethical – may vary considerably. Thus, it may be important to question whether a too-rigid interpretation of the "chain of mentoring" and its importance in building and maintaining ethical cultures within the laboratory may undermine the success of dual-use control initiatives. Of additional importance for any ethics educational initiative, this chapter shows that it is vital to avoid thinking of research groups of scientists as homogenous in the way they structure the social life of the laboratory.

In order to adequately interrogate these claims, it is necessary to first examine the notion of informal ethics teaching in science, how it forms an important aspect of building research integrity, how it is used in RCR education, and some of the issues associated with its application in this area. The chapter will then go on to investigate the successes and limitations of current aspects of dual-use education dealing with informal teaching, after which the fieldwork will be presented in support of the conclusions drawn in the chapter.

### 6.1 Informal Ethics Teaching in Science

As mentioned above, it is well recognised that the majority of ethics education for scientists does not occur within classrooms, but rather through informal processes within the laboratory. "Learning by experience" is a key element in the development of any research scientist, and extends beyond the achieving practical competence. It plays a vital role in facilitating the understanding of and integration into the ethical and social culture of scientific research. This tendency was well summarized in the 2009 NAS report, *On Being a Scientist: a Guide to Responsible Conduct in Research*. Briefly, the report suggested that "... beginning researchers learned the standards of science largely by participating in research and by observing other researchers make decisions about the interpretation of data and the presentation of results and interactions with their colleagues. ... They learned how the broad ethical values we honor in everyday life apply in the context of science. ... This assimilation of professional standards through experience remains vitally important" (NAS 2009: x).

The reliance on scientists learning ethical values *in* their environment and *from* their environment pervades most ethical pedagogical and capacity building initiatives as well as research on the subject. Either explicitly (such as IoM 2002) or implicitly (such as SCRES 2001), they promote learning by observation, informal instruction and mentoring. In doing so, the issues relating to mentoring, and the development of an environment that supports mentoring, become of particular importance.

Some of these issues were addressed in the 2002 report by the Institute of Medicine entitled *Integrity in Scientific Research*. This report emerged in response to growing concerns regarding the continued presence of FFP behaviour within life science research, and how the RCR model could be strengthened to combat misbehaviour. In doing so, the report critically addressed the roles of mentor and the institution in mediating the behaviour of individual scientists, mentioning that adherence to policies and procedures,

while necessary, are not sufficient means to ensure the responsible conduct of research (IoM 2002: 3). Thus, the report raised considerable questions regarding what could be done to promote research environments that fostered integrity and an ethical behaviour.

In particular, mentoring and/or supervising<sup>113</sup> are recognised to play an important role in fostering the social cohesion in science that keeps the profession strong (NAS 2009: 4). Indeed, in most cases mentoring is the primary means through which practical as well as cultural information is transmitted. In Western scientific research this practice has a long history, and has gradually developed into the modern system present in most academic institutions that includes a hierarchy within laboratories from the HoD, the Pls, the research scientists and postdocs, to grad students and technicians (IoM 2002). In most cases, the "chain of mentoring" is so entrenched within the laboratory structure that it passes without comment.

Within this "chain of mentoring" the PI plays a pivotal role in developing and maintaining ethical practices within research. Many different publications (such as NAS 2009) have elaborated on the responsibilities of PIs for ensuring that the professional standards of science are maintained within their research groups on a variety of topics such as treatment of data, research misconduct, laboratory safety, and sharing results. PIs have also evolved into the "first port of call" for providing assurance of ethical conduct to funding bodies, publishers, RECs and the public. Thus, all in all, PIs play a vital role in transmitting the variety of ethical requirements to their research team and ensuring that they are upheld.

Nonetheless, the PI does not work in isolation, and many reports such as *Integrity in Scientific Research* are also very explicit about highlighting the importance of the research environment in promoting good conduct in research.

<sup>&</sup>lt;sup>113</sup> In many instances, the mentor and/or supervisor also filled the role of PI on a research project. Because of this overlap, many documents and discussions use the term PI to denote those in a supervisory role, as will the rest of this chapter.

Research institutes have come to play an important role in mediating between the plethora of national and international requirements which govern research, such as governmental regulations, journal practices and policies, funding, human resources and practices of scientific societies, as well as a more general socio-cultural, political and economic environment (IoM 2002: 8). This is often done through RECs, who play an important role in the surveillance of research within the institution. Furthermore, research environments also have a crucial duty to provide and maintain channels for whistleblowing and raising concerns.

Reports such as *Integrity in Scientific Research* thus present a multifaceted view of how to foster good conduct in scientific research. Within this vision the PI acts as a lynchpin, as they crucially shape the immediate research environment within their laboratory. How ethical research environments are created, however, is by no means a well-understood topic, and mentoring remains a largely informal process of personal interpretation of leadership. Although reports such as *Integrity in Scientific Research* provide lists of duties for mentors<sup>114</sup>, few (if any) scientists go through any formal training to become a mentor or PI. How PIs thus meet the considerable expectations that are placed on them with regards to preventing misconduct and promoting good conduct within research remain open questions.

# 6.2 <u>Strengths and Weaknesses of the Teaching Through</u> <u>Experience in the RCR Model</u>

In research ethics education the combination of strong regulatory systems and clearly defined role responsibilities together with the promotion of subsequent "teaching through experience" form the basis of its approach to any long term promotion of research integrity. With regards to "teaching through experience", it is evident from the examination of RCR modules that this is primarily assumed

<sup>&</sup>lt;sup>114</sup> The recommendations included providing leadership in support of RCR, promoting productive interactions between trainees and mentors, advocating rule adherence, carefully and openly managing conflicts of interest and allegations of misconduct, and promoting education about research integrity (IoM, 2002: 5).

to occur through the "chain of mentorship" in which the PI plays the role of primary educator (Shamoo 2009). This is evident as many modules emphasise the importance of PIs monitoring students' behaviour, introducing them to the necessary regulation, and providing them with critical insight into potential ethical issues arising from their research.

Because of the clearly defined expectations of behavioural outcomes from research ethics instruction, this approach tends to work well. Using the example of animal research, it is clear that in order to ensure that beginner scientists conduct their research with integrity, the PI will have to ensure that the student is familiar with current regulations, has attended the relevant ethics course, and conducts their work according to the standards set by the institution. Furthermore, in the case of an ethical (or practical) dilemma arising during the research, the PI must be on hand to advise and guide the beginner scientist towards an acceptable solution. These activities are supported by the research institution, which ensures the presence of adequate regulatory guidance, an REC and sufficient ethical education for beginner scientists.

Nonetheless, such a system of teaching through experience is far from perfect, and the regular appearance of reports of FFP misconduct within the life sciences is a stark reminder. Despite the rise in research on RCR and scientific misconduct, and the development of regulations, guidelines and codes of conduct, there has not been an accompanying decrease in incidences of misconduct or misbehaviours (Swazey 1993). A recent study by Kornfeld which reviewed 146 US Office of Research Integrity cases over a 10-year period showed that none of the accused claimed that the offense for which they were prosecuted should not be considered research misconduct (Kornfeld 2012), suggesting that while the perpetrators did not lack the knowledge of misconduct, something in the ethical culture of the laboratory enabled them to mis-act knowingly.

Furthermore, and perhaps equally troubling, are a number of studies which identify a range of other forms of misconduct. These include duplicate publication, authorship misdemeanours, inadequate supervision, conflicts of interest, and financial mismanagement. In addition, other misdemeanours include sloppiness in research, oversights or failure to share research results (Korenman 1998, Anderson 2007, Nyika 2009, Novossiolova 2011), as well as "normal misbehaviours", including strategic game playing, decline of free and open sharing of information, sabotage of others, uncredited use of other's work, interference with peer review process, careless or questionable research, abuse of power in mentoring of students (Anderson 2007). The identification of such a vast range of misbehaviour within science has prompted considerable investigation into why it continues to occur.

These studies often suggest that it the lack of behavioural guidance, or the presence of competing patterns of behaviour that result in these misdemeanors. Such observations can be related to the concept of "ethical erosion" which has its roots in medical ethics. Briefly, studies on medical students by Christakis, Feudtner, Hundert and others all suggested that ethical principles taught within a classroom may be undermined by contradictory behaviour from peers and teachers *in situ* (Christakis 1993, Feudtner 1994, Hundert 1996). Such situations were observed to destablise the ethical development of medical students by forcing them to acquiesce (consciously or unconsciously) to situations that undermined or countered their ethical training. Ultimately this resulted in a loss of, or failure to develop, an appropriate professional identity.

These studies suggest that this "hidden curriculum" of alternate values played an important role in understanding the (un)ethical behaviour of the medical students. Such could also be the case within the life sciences, and it is possible that disjunctions in the ethical culture of laboratories and that taught in ethical education could be a significant contributing factor towards misbehaviour (Novossiolova 2011). Indeed, low levels of ethics education, as well the promotion of assessing hypothetical situations, or understanding of ethical principles, policies and rules (Anderson 2007), instead of issues arising in daily laboratory life, would seem to suggest that this is a feasible consideration.

Most studies on misbehaviour in scientific research observed that scientists were aware of the impropriety of their behaviour, yet attributed it to extenuating circumstances within the research environment (Kornfeld 2012), indeed pointing to a breakdown in the ethical climate. These included the influences of competition amongst scientists for position and prestige (Anderson 2007), publication pressures (Kintisch 2005), lack of mentorship (Wocial 1995, Anderson 2007, Wright 2008), ambiguities and everyday demands of scientific research (De Vries 2006), and perceived irregularities in distributive, procedural or organisational justice (Martinson 2005).

Thus, as mentioned by the NAS report: "... many beginning researchers are not learning enough about the standards of science through research experiences. Science nowadays is so fast-paced and complex that experienced researchers often do not have the time or opportunity to explain why a decision was made or Institutional, local, state, and federal guidelines can be an action taken. overwhelming, confusing, and ambiguous. And beginning researchers do not always get the best advice from others or witness exemplary behaviour" (NAS 2009: x). Such observations have heralded the growing commitment towards fostering integrity within workplaces, and integrity in science has become a subject of intense scrutiny as federal rules, institutional policies and informal practices all attempt to standardize it (Korenman 1998). Nonetheless, a lack of coherence in approaches towards improving the quality of mentoring and developing policies that acknowledge the important contributions of whistleblowers and which establish truly effective means of protecting them from retaliation (Kornfeld 2012) suggest the current situation is far from satisfactory.

For all the misbehaviour that occurs, however, it must be recognised that many mentors predominantly do make scientists aware of norms that sanction or forbid certain types of behaviour. Within research ethics, "teaching by experience" plays a role of fundamental importance in ensuring that students learn behavioural patterns that correspond to the national and international Nonetheless, the brief review of misbehaviours in research requirements. above suggests that more discussion is required regarding what exactly "teaching by experience" entails and what can be expected of it.

#### 6.3 "Teaching by Experience" as a Means of Fostering **Dual-Use Awareness**

As discussed above "teaching by experience", despite its problems, remains a powerful means of perpetuating RCR education. In part this could be because of the focus on preventing misconduct, rather than promoting good conduct. Indeed, the near global agreement on what constitutes scientific misconduct and a widespread acknowledgement of scientific misbehaviours make the prohibition of these behaviours relatively straightforward. In contrast, however, what constitutes "good conduct" is much less apparent. It may be suggested that what constitutes "good conduct" in science is influenced by the contextual influences of societal norms, priorities and customs.

Thus, promoting "good conduct" is subject to two main difficulties: firstly that there is less common agreement as to what exactly constitutes as "good conduct" in research and any definition should be recognised to have a strong contextual element, and secondly that there is far less understanding of how such conduct can be fostered within laboratories. In discussing "good conduct" it may be helpful to utilize some terminology developed in the field of business ethics. This field has a long history of examining the interplay between ethical behaviour and the context in which it occurs, and many studies in business ethics use the concept of an "ethical culture" in their analyses of work environments<sup>115</sup>. This model emphasises that ethical conduct is influenced by a

<sup>&</sup>lt;sup>115</sup> It must be noted that business ethics employs two different concepts to discuss the ethical context in organizations: ethical climate Victor, B., Cullen, J. B. (1987). A theory and measure of

combination of individual characteristics (values and cognitive moral development) and contextual factors (reward systems, rules, codes) (Trevino 1986). In so doing, it is situated within the broader field of organizational culture literature, which views the organisation as "both the medium and the outcome of social interaction" (Denison 1996: 653).

The ethical culture, as developed by Treviño (1986, 1990) focuses on the phenomenal level of culture – the more conscious, overt and observable manifestations of culture such as structures, systems, and organisational practices, rather than the deeper structure of values and assumptions (Trevino 1998). Thus, the ethical culture can be understood as the situational moderator of the relationship between the individual's cognitive moral development stage and ethical/unethical conduct. In this model it was proposed that "culture" was comprised of the organization's normative structure (norms about what is and is not appropriate behaviour), referent others' behaviour, expectations about obedience to legitimate authority, and the extent to which the organisation encourages individuals to take responsibility for the consequences of their actions (Trevino 1998). In addition, it must be observed that this culture comprises of "formal" (rules, codes, leadership, training etc), and "informal" (peer behaviour and ethical norms) systems.

Importantly, the model highlights that these contextual factors are important from a practical perspective, as managers have more control over these than individual values or moral development. This approach has led business ethics to rigorously interrogate what practical measures can be taken to foster ethical

ethical climate in organizations. <u>Research in Corporate Social Performance and Policy</u>. W. C. Frederick. Greenwich, CT, JAI Press.

and ethical culture Trevino, L. K., Youngblood, S. A. (1990). "Bad apples in bad barrels: a causal analysis of ethical decision-making behaviour." <u>Journal of Applied Psychology</u> **75**: 378 - 385.

<sup>.</sup> While these two constructs focus on strongly related dimensions of the ethical context, it has been suggested that "ethical climate" refers more strongly to observed unethical conduct in non-code organisations, while "ethical culture" is associated with code organisations. It is probable that both concepts will be of use for the life sciences, however this analysis will focus on ethical cultures.

behaviour within a work environment. Specifically, studies question how managers can foster an ethical culture within their workplace.

I believe that adopting a similar approach towards understanding "ethical cultures" may prove of considerable importance for the life sciences, particularly when discussing broad social issues. All laboratories, like businesses, may be said to have an "ethical culture" which guides daily research and mediates personal behaviour. These cultures, although heavily influenced by the PIs (managers, as it were) and the research environments, are also the product of the promotion of certain "good" traits of behaviours. Thus, as "ethical cultures" transcend misconduct and include discussions on good conduct, it may be that further examination on how they are established in laboratories will allow sufficient freedom to analyse how the global responsibility that lies at the heart of broad social issues may be perpetuated in research. Nonetheless, despite its probable utility, the notion of "ethical cultures", and the promotion thereof, have yet to make a significant appearance in ethical discussions, and discussions on fostering "good behaviour" are few and far between. Such is definitely the case with dual-use that continues to use an RCR-influenced emphasis of "teaching by example" as a means of perpetuating education.

Although there is little discussions regarding how or what should be "taught through example", dual-use discussions explicitly promote the idea of the PI as a key player in fostering new generations of dual-use-aware scientists. As the PI is generally the primary point of contact for funding questions, publication requirements and REC approval applications, there appears to be an assumption that the issues promoted in these initiatives will be transmitted by the PI to their staff and student and in some way a "culture of responsibility" will be established within these labs.

In making these assumptions, dual-use discussions rely on two issues: firstly that, in a similar manner to the RCR model, the presence of a "chain of mentoring" requires no further investigation, and secondly that the "chain of

mentoring" is able to deal with the obligation to transmit ethical issues as complex as the concept of dual-use (ie. fostering "good behaviour" instead of preventing misconduct). However, as noted by Cho: "[c]ontemporary research is nested in a plethora of codes, rules and laws. It is a challenge to inculcate the skills of responsible research let alone the more general set of nontechnical skills and virtues that ennoble science" (Cho 2006). Thus, it must be asked whether such a PI-centric approach is really suitable for transmitting the notion of global responsibility for dual-use at all. Some of the issues that I have identified are proposed below.

Firstly, that current approaches for the transmission of dual-use information to PIs and other staff members (outside formal education) include dual-use issues addressed on funding applications, publication reviews, institutional guidelines and so forth. It would appear that there is an assumption that the normative goals underpinning these initiatives will be critically understood by PIs and staff, and, furthermore, will be implemented within the laboratory to supplement the dual-use education received by students and staff. This requires that relatively abstract concepts and case studies be translate into daily practice – something which is by no means a simple process (Anderson, 2007). Therefore, PIs and staff, as well as students, would need guidance if they are to resolve real-life situations and translate abstract principles into practical solutions (Chambliss 1996) – something which has been slow in coming, particularly in light of the increasing dual-use regulations that PIs are forced to confront in daily research.

This observation is linked to the second one, that unlike RCR, there is little in the way of "misconduct" within dual-use that can serve as a benchmark for judging the success of the these informal methods of pedagogy. It is possible that, due to their experiences with RCR training, that the absence of such a benchmark could result in less pressure for PIs to conform. As mentioned by Trevino in her discussion on ethical cultures, the referent behaviour of others within an organisation is a vital component of building such environments (Trevino 1998). Thus, one must question exactly what serves as referent behaviour for dual-use "teaching through experience"?

Thirdly, the recent NSABB proposal of splitting research into "dual-use research" and that "of concern"<sup>116</sup> has been adopted by civil science funders, publishers, and organisations as they develop processes to assess the risks and benefits of individual instances of research (Rappert, 2008). Ultimately such an approach would exclude the vast majority of research from further formal consideration. This has the potential to present PIs with the impression that dual-use is a regulatory issue that can be solved by checking boxes off a list, rather than a topic which requires constant engagement and development, and could distort the manner in which dual-use is taught on a daily basis.

A final consideration regarding the reliance on a "chain of mentoring" in dualuse education concerns institutional support for "teaching by experience". Trevino noted that the organisation's normative structure, and the extent to which the organisation encourages individuals to take responsibility for the consequences of their actions are vital to the development of ethical cultures (Trevino 1998). In contrast to RCR, the institutional involvement in fostering awareness for broad social issues such as dual-use tends to be slightly nebulous and under-defined. It is generally agreed that it is the institutions are obliged to ensure that their staff are properly aware of the ethical, social and legal issues relating to their research (Sture, 2010), but how that is done is not clear. Aside from a commitment to developing and upholding a regulatory structure in line with national and international legislation, what duties the institution has for promoting dual-use – through educational initiatives, support for whistle-blowing<sup>117</sup>, the promotion of public engagement and beyond, remain

<sup>&</sup>lt;sup>116</sup> For the NSABB, the term "dual-use research is used to refer to new technologies and the generation of information with the potential for benevolent and malevolent purposes (NSABB, 2007: 2). In contrast "dual-use research of concern" refers to the "subset of life sciences research with the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten public health or other aspects of national security (NSABB, 2006: 16).

<sup>&</sup>lt;sup>117</sup> Recent studies on whistleblowing for FFP behaviours (which are, on the whole, more easy to identify) in research suggest that individuals raising awareness of misconduct often bear significant negative effects Braxton, J. M., Bayer, A. E. (1994). "Perceptions of research misconduct and an analysis of their correlates." Journal of Higher Education **65**(3): 351 - 372.

<sup>,</sup> Braxton, J. M., Bayer, A. E. (1996). "Personal experiences of research misconduct and the response of individual academic scientists." <u>Science, Technology and Human Values</u> **21**(2): 198 - 213.

<sup>.</sup> Thus, any discussion on ethical cultures in research also need to include the observation that mainly when most individuals are supremely confident of the integrity of their

unclear. Moreover, what role the RECs of these institutions should be playing in dual-use surveillance and awareness raising requires further examination.

Nonetheless, despite these considerable hesitations, "teaching by experience" through a "chain of mentoring" remains a key area in dual-use controls, which has been endorsed not only by policy developers such as the NSABB, but also by scientists themselves. A 2009 publication by the NRC and AAAS entitled *A Survey of Attitudes and Actions on Dual Use Research in the Life Sciences* provided baseline data from a poll of scientists in the USA. In this survey 87% of respondents agreed that PIs hold the primary responsibility for the initial evaluation of the dual-use potential of their research, while 86% agreed that PIs were responsible for training laboratory staff, students and visitors about dual-use. Such surveys clearly indicate the important role that PIs play in establishing a culture of dual-use awareness within laboratories.

How PIs and staff are to create ethical cultures of dual-use awareness within their laboratories is thus a complicated topic. Within a Western context, the problems associated with teaching broad social issues such as dual-use by experience can potentially lead to considerable difficulties for the PI and staff as they attempt to balance personal opinion with social expectations in an environment in which they already have manifold professional duties. In the following section the discussion is opened to include the problems associated with using this model of engagement in developing countries.

# 6.4 Developing Cultures of Dual-Use Awareness in Non-Western Environments Using Existing Approaches

Thus, from the section above, it would appear that the concept of "teaching by experience" is considered an important element in the aspirations to develop an

institutional systems will they consider blowing the whistle on bad practices. The problems of encouraging and supporting whistleblowing occur in all areas of science.

international culture of dual-use awareness and to ensure the perpetuation of dual-use education. However, based on the hesitations above, it must be questioned whether current approaches are able to deal not only with the intricacies of promoting "good behaviour" (rather than preventing bad behaviour), but also whether they are properly directed to facilitate the development of "ethical cultures" within laboratories. It would appear to me that these problems are compounded by the RCR-related approach to "teaching by experience" currently employed in dual-use discourse. This includes assumptions regarding the presence of "chains of mentoring" and an emphasis on the primary responsibility of the PI, the support of the research environment, and the emphasis on fulfilling role responsibilities. While problematic for laboratories in developed countries, it is easily apparent that these issues will be compounded in non-Western countries where the social structures of labs might differ markedly from the Western norm.

Studying the social structures of scientific research has a long history, and a considerable number of ethnographies demonstrate the uniqueness of each laboratory environment (the classic one was, of course, conducted by Bruno In recent years, a number of excellent comparative Latour in 1986). sociological studies of laboratory cultures have emerged which highlight national differences in the social structures of research, and its impact on knowledge generation practices. This is particularly well-examined in the work done by Sharon Traweek on the social differences between American and Japanese physics laboratories (Traweek 1988). Her study showed how social traditions (such as deference to elders) influenced how research groups were structured and interacted. Such studies emphasise the possible variations in ethical cultures and the social structures of research and make it difficult to assume any sort of homogeneity within the social structures of laboratories. These studies thus call into question a number of assumptions made by debates on "teaching through experience" that clearly have Western roots.

Firstly, it is important to question whether a "chain of mentoring" (in the traditional, Western sense of the term) be assumed to exist within the
laboratories? Can the presence of PIs, research scientists, postdocs, graduate students and technicians be taken as a given, or does this require further investigation? Romain Murenzi, the executive director for the Academy of Sciences for the Developing World (TWAS) recently highlighted a number of steps needed to help countries stymied by poor scientific and economic capacity. These included the need to improve the critical mass of professors with PhDs and doctorate level research, suggesting that the staff distribution in these institutions differs greatly from those in Western departments. Indeed, recent analyses of scientific research in Africa, for instance, suggest that there continues to be extremely low staff to student ratios in many countries, and the continually rising student numbers will serve to exacerbate this situation (Irikefe 2011).

Furthermore, Murenzi also highlighted the need for young scientists to be encouraged and supported to obtain research funds (Murenzi 2011). This, he suggested, would ensure the development of a young and vibrant class of emerging researchers and play an important role in revitalising the career ladders in African universities. Without new staff continually being added at the lower levels of the career ladder, it is difficult to see how dynamic and current research environments can be maintained. All in all, such observations strongly suggest that many developing countries have research structures that lack elements of the traditional "chain of mentoring", including sufficient PIs and young postdoctoral researchers.

Secondly, most Western interpretations of a "chain of mentoring" are characterised by relatively informal interactions between staff and students. Nonetheless, it is important to question whether these relatively informal approaches to colleague interaction are also present in other laboratories around the world? Many countries, such as was observed by Traweek in her studies in Japan, have appreciably more formal work environments. In such environments respecting hierarchies, avoiding questioning superiors, and similar behaviour are of considerably more importance than in most Western laboratories. The presence of such different social settings forces a re-

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examination of the assumptions that are made regarding raising dual-use concerns and establishing channels for such concerns.

Thirdly, although the concept of ethical cultures in scientific research is relatively new, speculation on how such cultures are formed in Western laboratories can be informed by current studies in business ethics. Nonetheless, in business ethics above it was noted that ethical cultures are taken to involve structures, systems and organizational practices (Trevino, 1998), and are therefore expected to vary considerably between businesses. Thus, similarly, it is important to recognise that ethical cultures within laboratories around the world are likely to be constructed and perpetuated in markedly different manners. While the awareness of the individuality of each laboratory is obvious in practical discussions, it is possible that this nuanced view of environments is lost in educational initiatives and policy documents, which necessarily have to provide generalized instruction.

Assuming a level of homogeneity within the social structures of laboratories around the world, as well as perpetuating an RCR-influenced approach to "teaching through experience" therefore clearly presents a number of problems for building an international culture of dual-use awareness. One must question whether making broad assumptions regarding the ability, agency and interest of PIs in raising dual-use awareness are potentially problematic. Furthermore, the assumption that individuals within research communities are able to voice, discuss and act upon any dual-use concerns that they may have cannot be taken for granted.

Thus, it is important to question whether the endorsement of "learning through experience" in dual-use discussions, and particularly the promotion of a "Pl-centric" one, may actually present considerable barriers to building engaged and active communities of dual-use awareness around the world. It therefore becomes important to question whether such an approach increases a sense of "not being part" of Western discussions of dual-use and thus dissociation, and

secondly whether it increases a feeling of helplessness, futility and ultimately ethical distancing.

Such issues became apparent during the fieldwork, through attempts to question PIs and staff about promoting dual-use awareness within their laboratories. Many of the PIs, as will be discussed below, felt poorly equipped to deal with these issues and perceived a greater bureaucratic presence of dual-use in daily research as simply a burden. Thus, as the fieldwork examines, one must question what can be done. In particular, I examine whether a better understanding of existing ethical cultures and the promoting of ethical behaviour in these laboratories, when contrasted to current dual-use approaches to perpetuating awareness, may yield some interesting alternative areas of engagement.

# 6.5 Accessing Existing Ethical Cultures Through Fieldwork

As with most of this fieldwork, the initial foundation for this set of investigations was grounded in my own personal experiences as a life science researcher at an African university. Despite my *alma mater* being one of the premier universities in Africa, it nonetheless struggled with many of the problems mentioned above. In particular, issues involving recruiting and retaining staff, recruiting postdocs, and maintaining staff/student ratios in the face of considerable governmental pressure to increase student intakes featured as elements in daily research life. For example, during my five years as a postgraduate researcher, not a single postdoc was employed by my department, which placed considerable strain on student-supervision relationships<sup>118</sup>.

<sup>&</sup>lt;sup>118</sup> This ultimately ended in more advanced students supervising lower students – I, for instance, co-supervised two honours students during my PhD.

Although the research environment in which I worked was not what would be termed "unethical", it operated with noticeable differences to the "chain of mentorship" in Western laboratories – something that became more apparent when I moved to the UK to conduct research. This included fewer PIs, far more senior technicians (who often had some supervisor capacity) and considerably more student responsibilities. Although my *alma mater* clearly prioritized research with integrity and ethical conduct, what it was able to do to support these priorities also differed significantly from the institution where I worked in the UK, particularly noticeable in the relative lack of formal ethical training.

Thus, having worked personally in two extremely different, and yet (to my opinion) equally ethical research environments I became very interested in the considerable variations in these ethical cultures of laboratories. During the fieldwork attempting to understand the social culture in the various laboratories became a key issue, and particularly observing how they differed from the Western-centric model promoted in dual-use discussions. Ultimately these observations led this critical analysis of how disjunctions between the existing and "Western ideal" states of social interaction could potentially created problems for PIs, staff and students when attempting to fulfil their dual-use role responsibilities.

My analyses of the social structures within these laboratories attempted to understand how the staff interacted and created group identities (with specific behavioural sanctions) for themselves. These observations were considerably informed by the time I spent with the labs as a group – during coffee breaks, lab meetings, journal clubs and seminars. After gauging the initial "lay of the land" I then proceeded to ask questions regarding mentoring, supervision, promotion of ethical behaviour and reporting of misbehaviour in both the interviews and during my informal conversations with participants.

Next, I attempted to contrast my understanding of the environments and the manner in which they functioned to the requirements set out by dual-use

controls on the PI and the environment. The manner in which the participants discussed these issues led to the development of two main themes with which the data was subsequently analysed: excessive pressures on the PIs, the problems associated with unsupportive research environments.

# 6.6 Observing Variations in Social Structures at Fieldsites

The site in the UK had a high number of postdocs and research scientists and a relatively low number of students. In observing the interactions between the members of this laboratory I identified the presence of what I would term a "typically Western" "chain of mentoring" (as discussed above). The HoD supervised a couple of PIs, who in turn mentored the postdocs and research scientists in their research team. There were only a few students who, although directly supervised by the PIs, were looked out for by the other members of the research group – particularly the postdocs. The HoD at this site was very engaged with the researchers in his laboratory, and I observed him at lab meetings and journal clubs, as well as conducting one-on-one meetings with various members of staff. He was one of the most enthusiastic supporters of my work and mentioned to me on a number of occasions the value that he saw in stimulating ethical discussion amongst his staff. This attitude definitely percolated down to his staff, and the PIs in particular mentioned his enthusiasm and support for these issues.

In contrast, both of the research groups that I visited in South Africa were quite small, having about 10 members – all of which were students aside from the early career PI. These, together with two (SA2) or three (SA1) similar research groups formed a bigger laboratory headed by a HoD. Both research groups impressed me with their dynamicism and the enthusiasm evident in the research group members. Two particular issues came to the forefront. Firstly (and possibly because both PIs were under 40), there was a high level of collegiality between the PIs and their students. Particularly in lab meetings and

journal clubs it was evident that every member of the group's opinion was valued, and all group members felt confident to share their views. In encouraging this behaviour the PIs appeared very approachable and engaged with their students.

Secondly, because of a shortage of postdocs and researchers, PIs depended almost entirely on their students to further their research interests. There were thus a quite high number of students conducting significantly varied projects relatively independently of each other. No doubt this contributed to the high level of professionalism and proficiency that I observed in the students. It is my opinion (backed by my own experiences) that in such situations students take on a lot of additional responsibility regarding their projects and therefore are considerably engaged with the project as a whole<sup>119</sup>. These sites thus presented a different alternative to the "chain of mentoring" seen at the UK site. Although the PI-student mentoring relationship was once again of primary importance, the PI was not able to rely on postdocs or research scientists to assist them in their duties.

At the KY1 site, however, there were very few students, and the majority of the staff were technicians (and did not hold postgraduate degrees). This correlated to the literature which suggested that limited opportunities for full-time employment and academic qualification often resulted in a very limited number of PIs (Irikefe 2011) controlling large numbers of technicians. My understanding of technicians based on my personal experiences in the UK and South Africa<sup>120</sup> was quickly proved insufficient for grasping the role that these individuals played in the KY1 laboratory, as many of the technicians played key roles in the various research projects of the laboratory.

<sup>&</sup>lt;sup>119</sup> Of course this situation has its problems too, which will be discussed below, particularly regarding lack of oversight or ethical erosion.

<sup>&</sup>lt;sup>120</sup> In the UK, and to a lesser degree in South Africa, technicians are not as common as in African countries, and usually work specifically on a project for a PI – often with little interaction with the students or other staff members.

My observations of the social interactions between the laboratory staff at the KY1 site definitely suggested a clear hierarchy. The HoD, who was also the PI on most of the grants for the laboratory, was not involved in the daily research. Indeed, during my entire time there the HoD was only present once in the laboratory – at a group meeting where he acted as chairperson. Similarly, the other two PIs did not tend to oversee daily research practices – an issue compounded by their offices being on a different floor to the laboratories. The technicians thus tended to form a relatively self-sufficient unit with a hierarchy of "senior" and "junior" staff who assisted each other in mentoring and advice. This system presented a very different picture to the "chain of mentoring" seen at the UK site.

The UG1 site presented an interesting middle ground between the KY1 and SA sites. Although there were a considerably higher number of students than at the KY1 site, all of these had spent at least three years previously as technicians and continued to be employed in this capacity (to varying degrees). Thus, in many cases, the students were actually writing up research that they had previously worked on as technicians, which placed them in a role of considerable responsibility and control. Interestingly, unlike the SA sites, there was a low number of PIs controlling the daily work of these students and many of them had primary supervisors at the foreign funding institutions (such as in London and York) who were the primary grant holders on their projects.

This brief overview of the social cultures of the fieldsites highlights an important consideration. Although all of the laboratories I visited impressed me with their commitment towards ethical research, how these ethical cultures were established and perpetuated varied considerably. When considering the African sites it was apparent that while the ideal of "learning by experience" underpinned the social structures of the sites, how this was interpreted was very much indicative of social, cultural and economic pressures. Thus, the traditional understanding of a "chain of mentoring" which aptly suited the social structures of the UK was not, in fact, a good representation of how the social structures were

established and perpetuated in these laboratories. Thus, one must ask, could dual-use approaches that rely on the presence of a "chain of mentoring" actually be undermining their efficacy?

## 6.7 Unduly Pressuring Pls?

In 2009 the Faculty Standing Committee of the Federal Demonstration Partnership (FDP) conducted a survey of PIs and co-PIs regarding the nature, size, and impact of the administrative tasks associated with their research projects. The responses suggested that 42% of the time spent by an average PI on a federally funded research project was reported to be expended on administrative tasks related to that project rather than on research (Rockwell 2009). Importantly, it was suggested that this burden was not the result of a few exceptionally arduous tasks, but rather the cumulative effect of the many administrative burdens imposed by different funding agencies, governmental agencies and academic institutions. These burdens included a number of different tasks, including ethics review and progress monitoring.

Surveys such as these suggest a situation in which the PI is already considerably burdened. Assuming that they will be able to transmit the values and requirements enshrined in these administrative tasks, and thus develop a coherent ethical culture within their research groups is thus by no means certain. Furthermore, how PIs allocate their time away from administrative tasks is by no means well understood. What percentage they spend on research and academic supervision compared to pastoral and pedagogical duties is, to my knowledge, unexamined.

In all five of the fieldsites that I visited, PIs were unanimous in bemoaning the amount of administrative tasks that they were required to undertake. Similarly, in all fieldsites many PIs mentioned their frustration at not being able to provide the level of personal development and pastoral care to their students that they

would ultimately like to. How PIs are thus supposed to cope with the expectations of creating cultures of dual-use awareness within their laboratories therefore, to my mind, required more careful examination.

Nonetheless, despite these similarities, in the African sites it was apparent that this pressure to provide ethical development to students was compounded by a number of additional issues. These primarily related to the absence of the traditional "chain of mentoring" discussed above, which skewed the burden of duties towards the PIs. In particular, this was due to the low number of PIs within each institution<sup>121</sup>, the high number of postgraduate students allocated to each PI, the absence of postdocs.

Furthermore, the relative instability of research funding structures within these institutions meant that extremely limited funding from governments was provided to core research costs<sup>122</sup>. This meant that in many cases high student numbers were needed by the institutions to generate income (Irikefe 2011). Therefore, academics are already struggling with difficult funding situations and high pressures to publish for international recognition often had very high teaching loads that further compromised their time with graduate students. Some of these problems and their impact on raising dual-use awareness are elaborated on below.

#### 6.7.1 <u>"I Have No "Right-Hand Man"</u>

The problematic issue of mentorship in developing countries has begun to be documented, and indeed this research has been mentioned several times in

<sup>&</sup>lt;sup>121</sup> Briefly, many African institutions are faced with an increasingly ageing staff, due in a large portion to the massive "brain-drain" of qualified individuals in the recent decades. This has extremely severe consequences not only due to the loss of expertise, but also as younger staff consequentially do not have mentors to foster and encourage professional conduct and responsible research.

<sup>&</sup>lt;sup>122</sup> While the South African government dedicates 1% of its GDP to research and development, the contributions of most other African governments to the research facilities in their countries are much less.

this thesis already. In particular this research highlighted the lack of experienced mentors (Fine 2007) and the absence of critical mass of professors with PhDs and doctorate-level research (Murenzi 2011)<sup>123</sup> as factors seriously hampering the development of robust research on the continent.

A common lament amongst PIs in all four African fieldsites was the lack of qualified postdocs, and the absence of a culture of postdoctoral research in Africa. My own experiences as a PhD student in South Africa had made me sensitive to the comparative lack of postdocs in my institute in comparison to the institutes that I worked in and visited in the UK. I therefore explicitly asked participants about their attitude to the absence of postdocs and its impact on their work.

From my discussions with students it became apparent that there was not only a lack of money for postdoc positions due to the funding structures present in the laboratories, but also that doing a postdoc in Africa was relatively unpopular. There was an overwhelming endorsement for attempting to secure a foreign postdoc position after the completion of the PhD. This situation was clearly elaborated by a PhD student in Uganda, who said the following:

"It's very, very difficult for someone to get into a postdoc for various reasons. First of all, much of the research is funded by foreign governments or donor funds, and the government's not much interested in this. If there are they only come in as a sort of intervention of a quick problem and someone else will do the follow up. So these funders, they don't put aside money for training, only for research, which is understandable because they can't have all the money for training people, so you'll find here people working for long, sometimes ten years in research, cutting edge research, and they remain where they are, unlike in Europe. You're expected to develop and write grants, but here it's not very common because there's not the possibilities. It's not that people are not good at what they do, it's that they need to look for scholarships out, which is difficult.

<sup>&</sup>lt;sup>123</sup> Murenzi, R. (2011) Give the new generation a chance. *Nature*, 474, 543.

At the end of the day, when they do get the scholarship they've been working for so long that they're seen as traitors for leaving us. At the end of the day they're not willed to return and work. They stay in the foreign place and work" (UG1-3: PhD student).

Interestingly, both in Kenya and Uganda, students also pointed out that having a PhD or a postdoc was not a prerequisite for lecturing, and therefore the salary difference between a postdoc or a lectureship was enough to entice most graduates away from the postdoc positions. *"We don't have the money [to hire postdocs], and we don't have the people willing to do a postdoc. Also, postdoc is not very old in the current system ... you can have a masters and be a <i>lecturer*" (UG1-1: PhD student).

The PIs that I interviewed were unanimous in lamenting the lack of postdocs in their institutions. While I had always considered the presence of postdocs as an important part of the composition of the laboratory, I was nonetheless surprised at the extent to which PIs discussed the impact of their absence. It appeared that the practical supervision and daily mentoring of students by the postdocs, as well as the research that they carried out independently of the PIs was considered vital by all interviewees. This situation was well detailed in a discussion I had with a young PI at the SA1 site.

"My peers at my stage, so early stage career researchers, in the US, their labs are run on postdocs whereas our labs are run on students because you simply don't have the money to employ a lot of postdocs, and there aren't a lot of postdocs to choose from. That's the main thing actually, there aren't a lot of postdocs to choose from because there simply aren't that many PhD graduates that stay in science [and remain in the country] and want to go to your lab, so that's the biggest hurdle for being non-competitive is the level of personnel that you get in that you have to train and spend a lot of time with early on, because graduate students are running people's labs and not postdocs. Also PIs have to spend a lot more time mentoring and nurturing students. It's such an issue. I'm getting my first postdoc next year and I'm so happy because she can help mentoring some of the junior students. People take time to nurture. They're either ignored – and most people are ignored by their supervisors – but if you really want to mentor and nurture them because they have real potential it takes such a lot of time at the expense of getting the results and publishing them and so on" (SA1-8: PI).

Thus, it would appear that the lack of postdocs had significant effects on the research coming out of the laboratory, but also on the mentoring of the students. Not only were students now a fundamental part of the PIs research plan<sup>124</sup>, but large numbers of them were relying on the same PI for mentoring and supervision. Thus, the practical demands on the PIs time made it probable that they were overworked, and therefore in less of a position to initiate ethical discussions.

The lack of postdocs, as an additional level of mentorship and guidance, appeared to have more far-reaching consequences than the practicalities of daily research. It would appear that the overburdening of the PIs by excessive numbers of students and the pressures associated with using students to generate research data meant that any ethics training was an additional demand on their time. It must be noted that although most of the PIs interviewed viewed ethics as a fundamental part of research, they bemoaned the current situation and their lack of ability to engage in explicitly ethical mentorship.

Perhaps unsurprisingly, the younger (under 40) PIs that I talked to more readily agreed on the importance of ethics in research. Nevertheless, when I explicitly asked them what they were doing to foster a culture of responsibility amongst their team, many of them referred to their own lack of mentorship in this area as a significant drawback. Indeed, as one South African PI said: "*[w]ell, I'm new* 

<sup>&</sup>lt;sup>124</sup> This has implications regarding the levels of responsibility that the students are afforded, and the types of projects that they are offered.

as a PI, so it's still something that I'm thinking about, and I certainly don't have any good examples to draw on because I never got the input" (SA1-8: PI).

These observations have serious implications for developing dual-use concerns within these (and similar laboratories). Firstly, the PIs at these institutions mentioned that they felt poorly supervised themselves, and ill-equipped to deal with the continually growing amount of responsibility placed on them. Secondly, in the absence of qualified postdocs the PIs had to take on high numbers of postgraduate students to bolster research outputs. Thus meant that they spent considerable time supervising the scientific aspects of their students, but consequentially had less time to spend on pastoral development.

A further consideration from these discussions was that the "daily contact point" that postdocs in the laboratory provide for students cannot be underestimated when considering how ethical cultures in laboratories are developed. Thus, from this examination it becomes apparent that is vital to critically interrogate the implications of assuming that PIs will be able to shoulder the task of fostering and perpetuating dual-use awareness without any help from a "chain of mentoring".

#### 6.7.2 <u>"I Never See My Supervisor"</u>

In light of what the PIs were discussing, it was unsurprising that lack of supervision was a regular complaint from the postgraduate students who participated in the fieldwork. When considering this issue from the students' point of view, it is important that a less-discussed element of supervision in African countries be highlighted: that of the student-supervisor contract.

Of course, the relationship between supervisor and student is a complicated one, and something that provokes heated discussion. Indeed, the style of the

relationship, duties of each party and level of closeness may be said to vary with each student-supervisor pairing. Nonetheless, in attempts to introduce some form of standardization into the process, many institutions in the UK and other Western countries have started listing the obligations of both student and supervisor in specially structured agreements<sup>125</sup>. Such documents explicitly list the expectations of both parties, and allow for a formal channel of complaint should the relationship prove unsatisfactory.

Such formalized codes of practice were not present at the UG1, KY1 and SA1 sites (although the SA2 site had a supervisor/student contract, it did not explicitly refer to expected duties). The lack of leverage of students over staff compounded with the heavy workloads of the staff appeared to work synergistically, and many of the participants complained about the low level of supervision they had received during their academic careers<sup>126</sup>. Anecdotes such as the one below were relatively common in conversations with students at both the KY1 and UG1 sites.

"When I did my masters I was supposed to take two years, but I took 4. [My supervisor] was having so much – he was coordinating so much other things – and really he will give you a small amount of time. So actually there is a lack of people to help in some of these things" (UG1-1: PhD student).

In Kenya and Uganda it was also frequently noted that "[g]etting a mentor is not easy, because we have few and the ones that are there are not interested in research, and the ones that are, their hands are full. So getting one and moving on is not that easy" (KY1-3: technician). This appeared to result in students being much less comfortable in criticizing their supervisors for fear of

 <sup>&</sup>lt;sup>125</sup> This relationship has also been dealt with in some detail by the 2009 NAS report *On Being a Scientist* (page numbers)
<sup>126</sup> It must be noted that none of the interviewed students complained about their present

<sup>&</sup>lt;sup>126</sup> It must be noted that none of the interviewed students complained about their present supervisors. While it may be that they were afraid of me reporting back to their supervisors, I think this unlikely. As the supervisors of the laboratories were proactive enough to host me and allow me to interview their staff, I think it is a reasonable assumption that these supervisors were more proactively involved in their students' development than most.

retaliation. As one PhD student in Uganda commented: "I don't like the structure of work here, actually I hate it, but we won't transform Uganda by running away" (UG1-1: PhD student). Such situations, where students rarely see their supervisors and are uncomfortable in raising concerns when they do, must necessarily be problematic when one considers the premium put on dual-use awareness being built through mentorship.

#### 6.7.3 <u>"Give Me a Box and I'll Tick It"</u>

During the fieldwork I noticed an interesting dichotomy in the way in which scientists approached ethical discussions. While willing to engage in discussions on dual-use and related topical issues, any suggestion of applying these discussions to their daily practice was met with frustration and sometimes hostility. This attitude was present in all five sites, but much more apparent in the African ones. It appeared that any form of ethics regulation was seen as something to be "got through" – despite any interest shown in our discussions.

In many cases it appeared that the scientists were overwhelmed by a surfeit of similar ethics questions on funding applications, memoranda of understanding, ethics reviews and so forth. In the absence of a coherent regulatory structure in which to place them, as seemed to often be the case in Africa, this plethora of questions soon lost any active content and became something that was simply "done" as a means to an end. One PI, when discussing the requirements of animal ethics mentioned that: "[a]t the end of the animal ethics there's a whole lot of points detailing the PI responsibilities, but no one ever reads it, and how do we make them? People simply don't read it, and that's human nature. Dualuse must avoid that – those issues – it must be effective somehow and not the usual window dressing." (SA1-12: PI).

It is thus difficult to see how any forms of "tick box" questions, as suggested by NSABB, will be of use in such situations, where already overburdened PIs need

to reflect on the content of the questions and communicate it to a large number of students. If, as was commonly the case, PIs believed that: *"[g]enerating the information is our responsibility. It's how we go forward. If someone else uses what we intended for good for bad it's not our responsibility. I don't think that the person generating the information should be responsible for everything that's done with it"* (SA1-10: participant 3), it is difficult to see how they will take the time to communicate a check-list to their staff.

In addition, how to keep staff motivated in often financially difficult conditions, where the possibility of promotion or improving qualifications is slim may prove a real challenge to some PIs. It must be noted that in many African countries, training laboratories at universities are poorly equipped, and often understaffed. It is thus likely that science students get little practical research training because research centres are often separate from universities (Irikefe, 2011)<sup>127</sup>. It would thus seem probable that the problems observed during the fieldwork were the "tip of the iceberg", as all the sites were dedicated research centres. In the case of these "regular" universities, it is possible that the "abstract" nature of dual-use issues – now even further divorced from an appropriate context – will appear hypothetical and meaningless (in a progression from the responses discussed in chapter 5).

In his work on RECs and clinical trials, Benetar discusses the creation of a "culture of compliance" amongst developing countries, where ethical requirements are treated as bureaucratic exercises rather than content-filled undertaking (Benatar 2002). In a similar fashion, it is difficult to see how a "tick box" approach when removed from a meaningful context, will contribute towards raising dual-use awareness.

<sup>&</sup>lt;sup>127</sup> Irikefe, V., Nordling, L., Twahirwa, A., Nakkazi, E., Monastersky, R. (2011) The view from the front line. *Nature*, 474, 556 – 559.

#### 6.7.4 Alleviating the Pressure on PIs?

These data, in my opinion, present a cautionary tale to current dual-use awareness raising initiatives. They suggest that considerable variations in how students are mentored within African countries may mean that the PI may not be able to have the "hands on" approach to ethical development that the "chain of mentoring" model expects. In such cases, placing additional (and potentially undue) pressure on the PIs may result in them treating any dual-use control requirements as a bureaucratic exercise, rather than a content-filled undertaking. Together with the tendency of African PIs to distance themselves from the concept (as discussed in chapter 4), these observations suggest that over-reliance on the PI may be a risky strategy.

Nonetheless, it is my firm opinion that all of the fieldsites that I visited in Africa achieved the highest ethical and academic standards. It was evident that an ethical culture of research existed within these laboratories, together with a high level of commitment to the standards set by the international science committee. This tends to suggest that ethical cultures in laboratories, just as in business, may be constructed in many different ways.

As mentioned above, the majority of the staff at the fieldsites in Kenya and Uganda were technicians. Most of these were no in possession of a postgraduate degree (largely due to the problems with financing a degree and finding a mentor), yet had a considerable amount of laboratory experience. These technicians formed the backbone of the laboratory, and often took on the bulk of the daily supervision of students. In these roles, the technicians in these laboratories differed significantly from those in developed countries<sup>128</sup>. In my own personal experience as a researcher it was the technicians who provided me with the bulk of my laboratory training, and also served as a "first point of contact" were anything to puzzle me during my research. It was definitely the

<sup>&</sup>lt;sup>128</sup> In the UK, for example, technicians tended to work specifically for the HoD or PI on the personal research of this individual.

technicians who controlled the daily functioning of the laboratory and ensured that our behaviour was up to scratch.

Nonetheless, despite the expanded role of technicians in African laboratories, they are not (usually) grant holders, they do not submit ethics approval applications, and they rarely receive a high level of ethical training (if at all). Given their pivotal role in African science, their proximity to the research, and their daily interaction with students within the laboratory, they would seem an ideal point of contact for any dual-use awareness raising initiatives – instead of the PIs. Furthermore, additional investigations into how ethical cultures were established and perpetuated in these laboratories would identify further areas in which the notion of a global responsibility and dual-use awareness could be promoted.

### 6.8 Environments That Don't Support?

Any discussion about building ethical cultures requires a careful look at the environment in which it is to operate. Indeed, studies in many fields of applied ethics have emphasized the importance of protection for whistleblowers, the presence of *ombutsman* representation, accessible leaders and adequate ethical oversight to be key factors in the development and maintenance of an ethical workplace (Trevino 1998). Within the life sciences this is no difference, and an increasing number of studies have emphasized the importance of these issues when examining integrity in research (IoM 2002).

In dual-use discussions these issues are of the highest importance, as one of the primary duties assigned to scientists is alerting relevant authorities as to the dual-use potential of research projects. In order to do so effectively, the importance of proper channels for the scientists to do so, adequate protection and support for them when they do, and effective institutional plans for dealing with the concerns cannot be denied. In the absence of such facilities, one must question what proportion of scientists would be willing to fulfil such a responsibility. Indeed, one must question whether it is actually fitting to expect them to do so at all, when they would put their careers in jeopardy with little probable positive outcome.

Although most dual-use discussions recognize the importance of these issues in achieving and maintaining dual-use surveillance they tend to be implicitly alluded to in educational materials. How scientists should operate in environments lacking one of more of these issues is rarely examined in any formal manner. From the field data it is clearly apparent that these issues were perceived as problems for the African participants, and directly contributed towards their reluctance to "get involved" with dual-use surveillance in any meaningful manner. These data show that these issues require considerably more attention, and practical initiatives to alleviate them if any significant strides towards a global community of responsibility are to be achieved.

#### 6.8.1 Ethics Committees and University Regulations

RECs play an extremely important role in the development and maintenance of ethical cultures in research. Not only do they mediate between research projects and regulatory frameworks, but also set standards for research and the behaviour of researchers. However, despite the position of key importance that RECs occupy in establishing and maintaining research integrity (IoM 2002), the structure of these committees and the scope of their activities vary considerably (Clarke, 2011). Indeed, although in many countries research institutions are required to have RECs, how the members are recruited, what type of review they conduct, and what they are mandated to act upon are usually decisions made by the individual institution.

In dual-use discussions RECs have a recognized position of importance, and will likely become increasingly significant as dual-use concerns continue to

make appearances in many different spheres, such as funding application forms. Probably due to the great degree of variation between the styles of committees, RECs activities however are not usually discussed in much detail during dual-use debates. Most dual-use discussions take it as sufficient that some form of ethical review is occurring in keeping with nationally mandated requirements - assumptions that are potentially problematic in Africa (Benatar 2002).

In order to better understand the regulatory environment of the institutions, and the manner in which it was governed, I attempted to speak to members of the RECs at each fieldsite. As expected, there were considerable variations between the committees in terms of style, composition and mandate. *"A challenge with ethics is that it has different sets of standards or procedures depending on the institution* (KY1-1: postdoc).

Many of the comments made by the ethics committees were, unsurprisingly, similar to complaints in developed countries – lack of funds, overburdening, and the complications associated with the voluntary nature of membership. As one member of the SA1 REC commented: *"It's difficult. All ethics committees suffer to a degree from this, and especially in the health sciences, people are so busy and they do this job in addition to everything else, and at the meetings people aren't fully prepared and haven't thought through or read, and sometimes that lack of preparedness makes for very poor debate which is problematical, so that the actual issues don't actually get talked about because they're still finding out what the issues are" (SA1-13: ethics committee). In addition, it was noted that" <i>"Maybe the standardization in labs is more weak. Anything that doesn't involve human participants is almost not scrutinized. It's seen as exempt*" (SA1-13: ethics committee).

All of the committee members that I spoke to lamented the lack of clear differentiation between a scientific and ethical review. It appeared that in many cases the committee was expected to provide both functions – despite the

obvious problems associated with this. In Kenya this was commented on not only by the REC member, but also by staff: "... *if we could have scientific review at a departmental level, I believe things would be better. Here I believe [the institution] needs to wake up and have their own [scientific review structures]*" (KY1-1: postdoc). The idea of a distinction between ethical and scientific review was also emphasized at the SA2 site. One of the participants was a previous member of the animal ethics committee and made the following comment: "I *was part of an animal ethics committee for two years, and one of the things that struck me more than ethical considerations, because I think often there were enough participants in these committees to decide if the work is ethically feasible or viable, but what struck me sometimes as something that has been ignored is whether the science justified the work that was being done. Are the conclusions that are going to be drawn from these experiments strong enough, of value enough, to the specific discipline to justify these kinds of work*" (SA2-9: PI).

In my conversations with the committee member at the SA1 site, she commented on the fact that, in her opinion, dual-use assessment would require some form of follow-up audit of research projects. She made the valid point that relying on the progress reports of scientists may not be sufficient to timeously flag up dual-use issues within research. None of the four committee members I spoke to, however, thought that follow-up audits (such as are done in the UK) would be feasible or advisable in their contexts. As the SA1 REC member commented: "[w]e don't have the capacity for [post-approval auditing] apart from clinical trials. It's very much a case of relying on the kind of responsibility taking that includes informing when there's disquiet or knowledge of things not being right so that we can look into it. The idea of the ethics monitoring, or policing, if you will, is impractical and may give those doing the work a way out "well you didn't tell us we were doing something wrong" (SA1-13: ethics committee).

None of the REC committee members that I spoke to were aware of the concept of dual-use. They all confirmed that dual-use was not part of the

standard ethics review in their institutes. Despite discussing dual-use at length, I did not feel that there was any particular interest from the REC members I spoke to. Indeed, comments such as the one below were typical.

"Dual-use issues in funding reviews would be extremely annoying. Especially if we had to start going through loops. If that happened it's gone wrong from the start. You can't filter everything – when it's quite obvious that we're not doing something that's dual-use. The only way it wouldn't be annoying if it was a tick. That would be ok. I guess it's the same as the animal ethics. We have a biohazard thing at the end, which is actually full of difficulties, which is also where the [department] is pissed off with us and we're clamping down. It used to be at the end, box 17: is this a biohazard?, which people could tick "no", but people don't take that seriously. And there's no biohazard committee at [the university], and they go away and where do they go? If it was on the level where we're putting into Wellcome and there was a question and "no" was sufficient, then it would be fine. If it had to go through a review board afterwards, that wouldn't be cool" (SA1-13: PI and chair of animal ethics review committee).

It would thus appear that few assumptions can be made about the coherence of ethical review within African universities. Thus, assuming that RECs will provide an extra layer of dual-use surveillance, offer guidance in dual-use dilemmas, and mediate between international dual-use requirements and their institutional requirements are all dangerously misleading.

Interestingly, on a final note relating to RECs, it must be commented on that in all four institutes there was a prevailing assumption that ethics approval from the REC correlated with the project being ethical. The logic behind this assumption is obvious, and in the absence of follow-up audits (such as are conducted in the UK), it is easy to see how such ideas become entrenched. It may be that this presents a distinct problem for raising dual-use awareness, as the idea of *continually monitoring* results for the unexpected consequences

leading to dual-use events (such as the mousepox experiments) contradicts this assumption.

#### 6.8.2 Whistleblowing and Protection

Dual-use discussions often mention whistleblowing as a responsibility of scientists, as an additional form of dual-use surveillance. It is important to note that, despite the considerable distinction between taking responsibility for one's own actions and whistleblowing on someone else, this issue has not been widely discussed in relation to scientists' responsibilities. How scientists raise concerns about their colleagues work, and what would motivate them to do so, are (in my opinion) extremely important, yet neglected, points.

Whistleblowing is a problematic undertaking under any circumstances. Ensuring that those who take it upon themselves to raise the alarm are not unfairly penalized for their concern is usually an on-going struggle. Indeed, within the life sciences there have been a number of high profile whistleblowing scenarios for FFP-related misconduct in which the whistleblower has suffered significantly for their troubles (Braxton 1994, Braxton 1996).

Nonetheless, in recent decades considerable attention has been paid to improving channels for whistleblowing and protection for whistleblowers by governments and research institutions in many developed countries. Unfortunately, in many developing countries such initiatives remain to be scarce, and many researchers in these situations are faced with fulfilling their perceived responsibility at considerable risk to themselves and their careers.

In relation to whistleblowing for dual-use concerns it is likely that these problems would be amplified. To be sure, raising a concern (however legitimate) about the future potential for research to be misused by a third party

is unlikely to be easy. Many of my discussions with the staff at the fieldsites tended to circle this point as I tried to determine what the interviewees felt were their responsibilities towards dual-use. Notwithstanding the robust discussions that were had on whether dual-use was *their* problem, little to nothing was mentioned about whistleblowing on their colleagues or superiors. When I asked about this, the answers always revolved around the lack of provision made for the protection of whistleblowing, and the (in their minds) inevitable negative outcome for the individual raising the alert.

Although whistleblowing – and the protection of those that do - (as mentioned above) is universally problematic, my conversations with scientists in Africa raised an important additional consideration. As funding was so scarce in these institutions - and importantly as it was usually neither local nor regular - many scientists were extremely hesitant to endorse any behaviour that would "rock the boat", so to speak. More than once participants suggested that the importance of having money to do research would make them reluctant to raise any concerns that they perceived as potentially causing them to lose (or not gain future) funding. It would thus appear that attempts to strengthen a culture of whistleblowing – or indeed any which endorses raising dual-use concerns – would require funding bodies to explicitly address these issues in their memoranda of understanding. Not only, it must be noted, in the duties of the scientists to raise these concerns, but the commitments of the funding bodies to support them and to ensure that their funding is not jeapordised by their actions.

#### 6.8.3 Static Hierarchies in the Work Environment

The excessive emphasis of the hierarchical structure in science is something that is often obliquely referred to in discussions on scientific misconduct. There have been a number of studies that refer to misconduct being linked to problems within the laboratory hierarchy system (Anderson, 2007a, 2007b, 2007c). These include static hierarchies that do not allow for career progression, unsupportive superiors who place undue pressure on

subordinates, or hierarchies that do not support good mentorship and result in individuals being isolated from their superiors.

This problem is undoubtedly present in laboratories around the world, and in no way is representative solely of the institutes in sub-Saharan Africa. Nonetheless, it became apparent during the fieldwork in Kenya and Uganda that this was a broadly noted concern – not only within the institutions visited, but in many other institutions within those countries. A large number of the participants complained explicitly about the difficulty of progressing along the career trajectories.

One of the participants in Kenya, when discussing the hierarchies within academic institutions related their static nature to the problems within governments. He had previously worked in Uganda, and described the situation there, saying: "[w]hen you go to Uganda they used to have a two-year term [for the president], and now they've changed it to nothing. The president's just come back – you can't expect anything to change" (KY1-6: quality controller). This statement correlated with my experiences both in the fieldsites, and at other institutions visited – that lack of political will, and a pervasive culture of political stagnation influenced the vigour of these institutions.

Particularly within the KY1 site<sup>129</sup> many of the participants complained at length about the difficulties of moving up the career trajectory. Many of the participants made statements similar to this: ".. *like myself if I take as an example, I'm going to do a postdoc [position sponsored by IAVI]. When I look around, I want to teach and open my own research but the problem is that there is this contractual employment and you are not on equal terms as someone with a permanent position, so you are in a dilemma – where are you going to be absorbed. So maybe you can get a lecture position, but we don't have an arrangement like you have this experience and this is how you continue - there is a gap – career development and capacity" (KY1-1: postdoc).* 

<sup>&</sup>lt;sup>129</sup> A situation that appeared to correlate with my experiences in other Kenyan universities.

This static career trajectory appeared to be compounded by the difficulties which most of the participants reported in attaining higher qualifications (discussed in chapter 5). Discussions I had with participants regarding promotions indicated that although advanced qualifications (MSc and PhD) and publications were vital to chances of promotion, many felt that they were not presented with the opportunities to fulfil these criteria.

It was telling that in all the discussions about hierarchies, none of the participants mentioned possibilities of changing the current system. Many participants recognized that: *"[b]eing alone you can't change the system. You just become a problem to the institution. It has to come from above. If you come somewhere personally and tell them about standards you are causing problems. You need the institution to tell them"* (KY1-1: postdoc).

How promoting dual-use awareness and raising dual-use concerns can be endorsed in communities of scientists where there is a definite possibility of backlash and severe career implications remains to be considered. Indeed, a better understanding of how scientists forge careers for themselves – from postgraduate students to HoDs - in these scientific communities will be valuable for future dual-use initiatives.

## 6.9 Styles of Ethics Education

As mentioned above, all of the laboratories that I visited impressed me with the integrity with which they conducted their research. Despite the systemic problems apparent at some of the sites (such as static career hierarchies), all of the participants appeared to be genuinely committed to conducting research to the best of their ethical abilities. However, as this chapter shows, the manner in which these laboratories created and maintained their ethical cultures differed

considerably. In contrast to the PI-centric, "chain of mentoring" version which was present at the UK site, the African sites differed considerably in regards to *who* was conducting the research, *how* an ethical tone was set, and *what* scientists did to maintain these cultures.

Although there was little doubt that students at the different sites were learning responsible conduct in research through experience, at the African sites these lessons were not necessarily from the PI, but often from highly trained (and relatively independent) technicians or senior students. The high student/staff ratio and the low number of PIs at these sites made this a practical necessity. Such a situation can work very well for preventing misconduct, if students and technicians are well briefed in the regulations surrounding their work. In the fieldsites that I visited, there was nothing to suggest that this was not the case, and indeed I was impressed with the professionalism and maturity of the students and staff at the African sites.

Although suitable for preventing misconduct, this chapter has already questioned whether a considerable reliance on "teaching through experience" is a suitable and effective means of perpetuating a culture of dual-use awareness. In particular, as mentioned above, fostering a sense of global responsibility and awareness requires the PI to have received a considerable level of ethical education and to endorse the value of raising dual-use awareness. Furthermore, the lack of minimum levels of behaviour and the promotion of a "tick box" mentality for ethical checks makes it very difficult to see what "good conduct" the PIs are expected to promote.

Nonetheless, dual-use education continues to rely on "teaching through experience" as the primary means of perpetuating the lessons taught in awareness raising initiatives, and places considerable emphasis on the duties of the PI to transmit and reiterate dual-use issues that are becoming prevalent on funding and publication applications. Such a situation has obvious

limitations that become even more pronounced in developing countries where the "chain of mentoring" differs markedly from that in Western laboratories.

Thus, this fieldwork raises an important issue: is it useful to rely on PIs to foster daily dual-use awareness in their staff and students? If not, as I would suggest is the case, what alternative is available? In response to this question I once again refer back to the concept of an "ethical culture" in laboratories. Although this concept has considerable attention in business, it remains considerably under-explored in science ethics. It refers *holistically* to the structures, norms, and individual interactions that contribute to a pervasive culture within a business that influences personal behaviours. In this manner, it extends the work of Stanley Millgram and Phillip Zimbardo, emphasising the influence of the environment on individual personal choices.

It would appear to me that a better understanding of how ethical cultures are established and perpetuated within laboratories (as they undoubtably are) would contribute to discussions on ethical behaviour in a number of ways. Firstly, that it would allow contextual variations in "chains of mentoring" and laboratory hierarchies to be explicitly considered. Thus, by initiating discussions on how "ethical cultures" are established in laboratories it would become apparent that the PI is not necessarily the primary driver of ethical behaviour within laboratories. Furthermore, examining the "ethical culture" of the laboratory would explicitly highlight deficiencies within the research environment (such as the absence of protection for whistleblowers) that would alter ethical behaviour.

Secondly, using the notion of an "ethical culture" would allow concepts like "responsibility" to be examined as a whole, instead of restricting the focus to how individual item of information (such as dual-use awareness) are transmitted into the laboratory. Building up a more holistic understanding of how responsibility is promoted, and what is promoted as a result, within laboratories would allow a better understanding of how the concept of global responsibility (which, of course, underpins dual-use discussions) may be fostered within research.

Thirdly, the notion of an "ethical culture" allows for discussion on "good behaviour" and the achievement of ethical goals, rather than limiting discussions to the prevention of misconduct and the minimum standards of behaviour. This is an important distinction that I have reiterated throughout this chapter, and a better understanding will prove invaluable to future discussions.

The notion of an "ethical culture" within laboratories, I am aware, remains a rather nebulous concept and requires considerable further investigation. In particular, how the heterogeneity of these cultures (by virtue of the variations in social structures and methods of informal teaching) makes it difficult to see how the concept can be actively addressed in educational and awareness raising initiatives for dual-use. Nonetheless, it is my proposal that, as a whole, ethical education for scientists – particularly for broad social issues – needs to focus on this concept. How laboratories establish and perpetuate ethical behaviour is of no small importance and needs to be considered in a more holistic manner.

# 7. <u>Reassessing Current Approaches to Teaching</u> <u>Ethics in the Life Sciences</u>

In the preceding fieldwork chapters the issues relating to teaching broad social responsibility to scientists raised in chapters one and two were interrogated empirically. A close analysis of the fieldwork transcripts and observation data exemplified the theoretical limitations of current approaches identified in chapter one and two. The fieldwork demonstrated that a current lack of sensitivity to the content of ethical principles, the context of research, and the variations in social cultures of laboratories all have the potential to considerably undermine educational initiatives – particularly in developing countries where these factors are acute.

At the end of each chapter I offered a number of brief suggestions as to how such problems may be usefully confronted. Unfortunately, as would be evident from these comments, I believe that only so much can be achieved through "tweaking" current approaches. Indeed, as argued throughout the thesis, it may be useful in the future to examine alternatives to the promotion of a global scientific ethics. Indeed, in line with current developments in general ethical thinking, it is perhaps time that scientific ethics questions whether principalism and the promotion of global ethical norms are actually the best way forward.

As discussed in chapter four, a number of scholars, such as Alasdair MacIntyre and H. Tristram Engelhardt, have suggested that the increasing secularization of ethics and the abandonment of theist-oriented ethical models has resulted in a situation in which there is no objective way to decide between competing moral theories. Thus, at best, modern philosophy should be recognized to be pluralistic and emotive. If this is to be the case, they question how any ethical discussion can be anything more than a competition of opinions. In the latter half of the 20<sup>th</sup> century virtue ethics has been revived by a number of different scholars as a means of confronting the problems associated with the gradual secularization of ethics (Pellegrino 2007: 63). In light of the problems

associated with the notion of a "global scientific ethics", it is therefore possible that virtue ethics may be able to contribute significantly to current and future discussions.

In this chapter some of the issues raised by this thesis are summarised and reexamined. In particular, some elements of virtue ethics are used to suggest an alternate course for current discussions, and a means of reframing current ethical perceptions in (and of) the life sciences.

# 7.1 <u>Reexamining Current Perceptions of the Life Science</u> <u>Community</u>

In both the theoretical and empirical research presented in this thesis I questioned the notion of a "global scientific ethics" and the implications that it has for the developing field of life science ethical. In my analysis I proposed that not only is a "global scientific ethics" unlikely to be established, but also that the promotion of this notion in many ethical discussions is detrimental to some current educational goals.

Instead, I suggested that current ethical discourse should take into account the moral heterogeneity of the global scientific community, and the contextually informed manner by which ethical issues are understood by these communities. Attempting to frame this statement in light of previous ethics research, I made use of H. Tristram Engelhardt's notion of "moral communities" as a means of understanding the flow of ethical discourse around the world.

Nonetheless, despite the utility of the notion of "moral communities" and *content* of ethical principles, it is important that any discussion not lose sight of the fact that scientific research is a very practical undertaking which can produce significant harms and requires a level of regulation and legislation. Thus, the question arises: how can moral communities be understood in science if we are

to preserve the internationality of science and the free and open exchange of information around the globe?

This section presents a brief answer to such a question. Firstly, by critically examining the concept of moral communities and how it may be successfully applied to the life sciences, I hope to briefly introduce an alternative to the notion of a globally homogenous scientific body. Secondly, by introducing the virtue ethics concept of a "practice" as a means of understanding research I suggest that there is indeed a way of promoting a unifying approach to science that takes contextual differences into account without lapsing into relativity.

## 7.1.1 <u>Moral Communities Within the Life Sciences and an Alternative to</u> <u>Global Ethics</u>

H. Tristram Engelhardt, together with a number of scholars such as Alasdair MacIntyre, have suggested that the increasing secularization of ethics and the abandonment of theist-oriented ethical models has resulted in a situation in which there is no objective way to decide between competing moral theories. Thus, at best, modern philosophy should be recognized to be pluralistic and emotive. If this is to be the case, they question how any ethical discussion can be anything more than a competition of opinions.

It is precisely this recognition of the intractability of moral and bioethical pluralism that presents such a challenge to any notion of a "global, secular ethics" – although it is precisely this intractability that has come to characterize many modern ethical discussions. Instead, in keeping with many other virtue ethicists, Engelhardt recognizes that communities – and indeed individuals – are separated by divergent moralities because moralities diverge in terms of how they are regard the good, the right and the virtuous (Engelhardt 2011: 250). As he suggested: "[a]n actual content-full morality cum an actual content-full bioethics requires a cluster of settled moral judgments grounded in particular rankings of values and goods, as well as of right- and wrong-making

conditions. ... Also, just because all moralities and bioethics may be concerned with the good it does not follow that all moralities share the same understanding of the good" (Engelhardt 2011: 251).

He goes on to suggest that: "[t]he point is that we are destined to live with moral and bioethical differences, because content-full moral and bioethical controversies are irresolvable by secular sound rational argument, because we do not share common moral and metaphysical premises or rules of experiences. As a consequence, we neither share a common understanding of moral experience nor possess a common moral experience. Therefore, we cannot resolve our bioethical controversies by secular sound rational argument. At best, we can enter into a sparse practice without moral content through which persons collaborate with the mere authority of common agreement" (Engelhardt 1986, Engelhardt 2011: 252).

In attempting to confront these problems, Engelhardt suggested that modern ethical discussions be viewed instead as occurring between "moral communities" who ascribe *content* to the *content-poor* ethical principles on the basis of their socio-historical context. He suggests (in line with Hegel) that in order to offer more than empty moral platitudes one must enter into a particular moral community and embrace its particular viewpoint so as to possess a concrete understanding of the right and the good. Only within such a particular socio-historically conditioned context can morality (or ethics) gain content (Engelhardt, 2012: 98).

Using such an approach, it is possible to see (as demonstrated in chapter four) how ethical principles may be attributed different *content* by different communities of scientists – an important observation for international ethics discussions. Furthermore, by using "moral communities" to refocus the locus of power in international ethics discussions as (according to Engelhardt), the authority of ethics is negotiated by the community in which it is to be applied. Therefore, the autonomy of a moral community is of paramount importance if

one is to allow them to develop *content-full* interpretations of ethical principles that are informed by their specific socio-historical context.

The fieldwork that I carried out in this thesis, strongly suggests that the concept of moral communities in the life sciences may be of particular importance to discussions that attempt to move beyond the notion (and limits) of a "global scientific ethics". The results in chapter four demonstrated that the *content* of the ethical principles utilized in dual-use discussions varied considerably between the different groups of scientists. Thus, separated as these groups of scientists were separated by their socio-historical context, the application of the term "moral communities" to these different groups of scientists seems a useful means of understanding these disjunctions.

Introducing the concept of moral communities to life science ethics discourse (as an alternative to views that present scientists as a largely homogenous body) has, to my mind, a number of different advantages. First and foremost, it re-emphasises the insufficiencies of the notion that scientists around the world can be referred to as a homogenous body. As ethics discourse often has a tendency to refer to "scientists" of the "scientific community" without specifically identifying who they are referring to, this will no doubt be of considerable importance for future discussions.

A second advantage is that moral communities are necessarily linked to the notion of *content-poor* and *content-full* interpretations of ethical principles. Thus, focusing on moral communities and not on a homogenous body of scientists makes it very difficult to perpetuate the notion of a "global scientific ethics", or indeed any assumption that ethical principles will be similarly applicable in any laboratory context around the globe. By emphasizing, instead, the different ways in which *content* can be ascribed to ethical principles it opens up a new area for considerable discussion – and potentially a means of minimizing the problem of "talking at cross-purposes" which presents a problem to international ethical discussions.

Within this thesis I have made considerable reference to the notion of "role

responsibilities" as a means of understanding how responsibilities are presented. I have suggested that although role responsibilities are intimately linked to a specific socio-historical context and attributed to a specific profession by the surrounding population, this is often poorly acknowledged. Indeed, particularly in RCR, I suggest that designations of responsibilities that should be understood as role responsibilities are instead presented as globally applicable responsibilities. A third advantage of using the notion of moral communities in the life science ethics is that by bringing the context of research to the fore it will be more difficult to do such things. Indeed, with the discussion on the *content* of ethical principles and the autonomy of moral communities it is hard to understand how role responsibilities could be transmitted between communities without serious negotiation.

Nonetheless, understanding moral communities – how they may be designated, perpetuated and how they relate to each other – is difficult. Moreover, understanding how these moral communities may be brought together in some manner to take into account the need for openness, freedom of research and international harmonization is no easy task. If one allows the autonomy of moral communities to be of paramount importance in ethical discussions (as suggested by Engelhardt), how is it possible that relativism can be avoided in ethical discussion? In this, it is possible that utilizing a concept from virtue ethics may prove particularly fruitful.

#### 7.1.2 Making Use of the Idea of Science as a "Practice"

One of the main problems of the notion of moral communities is that it is sometimes difficult to see how they relate to each other, and how ethical issues can be successfully negotiated between them. In this, the application of moral communities to life science ethics is no different. Current notions of the life sciences tend to trade heavily on the assumption of a united body of practitioners, and it is difficult to see how such a perception could include autonomous moral communities.

It is possible that virtue ethics may provide a useful alternative that would successfully ameliorate such problems, by reframing scientific research as a practice with a specific telos. In this, MacIntyre's work on the concept of practices is particularly useful. He defines practices as "any coherent and complex form of socially established cooperative human activity through which goods internal to that form of activity are realized in the course of trying to achieve those standards of excellence which are appropriate to, and partially definitive of, that form of the activity, with the result that human powers to achieve excellence and human conceptions of the ends and good involved are systematically ended" (MacIntyre 1984: 187). Medicine is a good example of such a practice, as it possesses and internal good, a set of rules and obligations related to that good, and a set of virtues requisite for achieving the internal good and without which that good is unattainable (Pellegrino 2007: 74).

For the life sciences, the *telos* of science could be taken to be something similar to "harnessing scientific investigations for the benefit of mankind while respecting the responsibilities towards humanity and nature". Thus, scientific research could be understood as a: "coherent and complex form of socially established cooperative human activity through which goods internal to that form of activity are realised in the course of trying to achieve those standards of excellence which are appropriate to, and partially definitive of that form of activity, with the result that human powers to achieve excellence, and human conceptions to the ends and goods involved, are systematically extended" (MacIntyre 1985, 187).

In a similar manner to Pellegrino's (2007) assessment of medicine, it is possible that a number of different goods could be identified for research such as the scientific good, the good for humans, and the spiritual good. The presence of a *telos* and specific *goods* internal to scientific research as a practice would thus present a means of unifying the diverse moral communities.

Similarly, as a practice, life science research could be seen to be associated with a number of virtues which could provide guidance for professional ethics by considering professional pursuits are distinct human activities in which virtues
and ends can be linked (Pellegrino 2007: 63). Furthermore, by using Gertrude Anscombe's suggestion of virtue and vice rules ("v-rules") may prove particularly helpful. These pairs of rules (while of course culturally relative) provide good guidance on how vice may be avoided and pick out actions that are right or wrong (Hursthouse 2012). As these rules are essentially the behavioural guidelines within a specific context, they allow virtues to be contextually interpreted without lapsing into relativity. Essentially, these rules are a tool that allows discussions to recognize differences in behaviour between different communities of scientists while also recognizing the constancy of the virtues contributing towards the *telos* of science.

Presenting science as a practice may prove particularly useful – particularly when discussing regulations and legislation. By focusing on the *telos* of science and encouraging discussions on the virtues necessary for achieving it would make it possible to provide learners with a comprehensive understanding of how and why specific areas of science fit together. Furthermore, it would allow students and others to critically engage with foreign legislation by using the focalizing lens of a *telos* for science.

Another advantage to presenting science as a practice and not a profession is that by being associated with specific virtues it is possible to initiate conversations with scientists on "v-rules" and achieving a "golden mean". The concept of virtue thus offers two important considerations for discussing professions. The first is the emphasis on discussing professions in terms of the active acquisition of virtues, and not (in contrast to other ethical systems) to relegate virtues to the position of mere admirable traits. Secondly, virtue ethics highlights that professionalism centres on continually striving for the golden mean of virtues in an on-going process of self-improvement in which the context plays an important role. Furthermore, as referred to above, virtue ethics provides a convenient means of discussing cultural variations (as embodied by "v-rules") without lapsing into relativism. This is an important consideration, as within other ethical systems the focus on rules/duties or consequences often provides a much more strictly defined scope of behavioural options.

While the notion of a profession as a practice has become a topic of discussion within medicine, law, ministry and similar professions (Pellegrino 2007), it has yet to be systematically suggested in relation to scientific research. It would appear to me that the concept of virtues (as opposed to principles or norms) might be a novel and useful means of scientific research as a practice. Nonetheless, what virtues would be important for scientific research would require considerable further investigation.

### 7.2 <u>Re-Contextualising Discussions on Research</u>

Refocusing attention away from the possibility of a "global scientific ethics" and towards the more nuanced approach that moral communities provides also allows deliberations to focus more directly on the considerable social, historical, regulatory and legal differences.

As discussed in chapter one, debates in research ethics rarely explicitly excavate the influence of contextual differences on the ethical development of scientists, giving the impression (intentionally or unintentionally) that a Western-centric approach is applicable globally. This, as a result of the focus and history of research ethics, has left a lasting legacy on life science ethics and which is particularly apparent in the discussions on broad social issues that tend to implicitly assume a Western-centric approach. However, contextual variations – particularly in discussions on broad social issues such as dual-use – are of considerable importance in building ethical awareness and perpetuating ethical education. The fieldwork presented in chapter five specifically addressed this issue and highlighted how systemic issues brought about by deficiencies or variations in the research context had a considerable effect on scientists' ethical development.

Nonetheless, how such a nuanced approach can be adequately addressed in ethics education remains a challenging subject. In this section I propose how variations in research contexts may be brought to the foreground in ethical discussions by changing the manner in which responsibility is commonly presented to scientists. Furthermore, I suggest that such a change in <sup>326</sup>

responsibility rhetoric would be further strengthened by the inclusion of the concept of *phronesis*, or "practical wisdom" from virtue ethics.

# 7.2.1 <u>Appreciating Variations in the Regulatory-Physical Research</u> Environments of Laboratories

In chapter five I used the fieldwork data to critically examine the influence of the regulatory-physical research environments on how scientists approached and accepted the concept of dual-use. The analyses clearly indicated that not only did considerable variations exist between the research environments at the different fieldsites, but also that these variations considerably influenced how scientists discussed the concept of dual-use, and how they related the ethical issues of dual-use to their own research.

The variations in environments that I encountered led me to suggest an alternative means of viewing the distribution of responsibility. Instead of a clear distinction between individual and collective responsibilities, I am inclined to favour Larry May's interpretation of a "web of commitments". Such a web, I believe, more adequately demonstrates the plethora of different responsibilities that scientists have to their work, their colleagues, and the society that supports them.

In order to clarify his position, May proposed that individual responsibility viewed as a "web of commitments" to different groups, which presents multiple, perhaps even conflicting, commitments, not from the challenges of differing professional and personal identifies and even incompatible epistemic cultures and moral priorities (May 1996, Malsch 2009). Thus, through this "web of commitments" individuals make legitimate negotiated compromises, and it is vital that possible conflicts within these "webs" are made explicit to avoid ethical crises. May emphasises that these negotiated compromises depend not only on the personal integrity of the individual, but also on the solidarity and support of the groups and organisations. Thus, in order to expect individuals to obey the demands made of them, groups must offer support for them.

This solidarity within groups, May proposes, develops from individuals identifying with the group. Within the discussion of dual-use responsibility – and indeed most discussions on life science ethics - this is a key, yet often mute, point. Little attention is given to whether scientists identify with the greater science community, or whether they view themselves as "removed" or "apart" from the fold. In the fieldwork it was definitely apparent in the manner in which participants described themselves in relation to the broader scientific community.

Using May's "web of commitments" within the life sciences – particularly for broad social issues – may be an effective manner of framing responsibility in ethics education. Not only does it emphasise that scientists may have considerably different responsibilities in different research contexts, but also that they must critically learn to balance these responsibilities.

In this, group solidarity is paramount. Thus, it would appear that "moral communities" of scientists need to critically develop an awareness of the challenges within their own research context, and to provide support for individual scientists as they navigate their "webs of commitments". By feeding back the challenges and pressures of a particular research environment, the specific "moral community" will be able to stimulate discussion on how national and international regulation does and does not work, and where the regulation falls short of supporting the individual scientist.

In this manner, it is possible that a considerable amount of the "ethical erosion" and "ethical distancing" discussed in chapters five and six could be ameliorated. Scientists, by having access to discussions on "webs of commitments", conflicting responsibilities and priorities, and environmental issues impacting on the realization of responsibilities, will be able to learn from each other and realize that they are not alone.

#### 7.2.2 Introducing the Idea of Practical Wisdom

Once again, virtue ethics is in a strong position to contribute towards this

problem due to its firm emphasis on "*phronesis*" or *practical wisdom* in the daily application of virtues. The concept of *phronesis* was introduced by Aristotle to describe the need for continual reflection and assessment within a virtuous life. This "practical wisdom" emphasizes the difference between becoming good as opposed to merely understanding what the good might be, and requires a deal of experience and pragmatic knowledge.

It is important to note that within virtue ethics a virtuous adult is not considered infallible. On occasion it is possible that they may fail to do what was intended through lack of knowledge. Thus, unlike other ethical systems, there exists a greater modicum of leniency for the failure to follow the ethical pathway. However, it must also be noted that this leniency can only be exercised on occasions in which the lack of knowledge cannot be considered culpable ignorance. Thus, virtue ethics places an emphasis on providing individuals with the knowledge to be able to exercise their practical wisdom in daily situations, rather than providing them with lists of duties or rules that need to be followed.

Furthermore, virtue ethics places a considerable importance on the responsibility of every individual to gain knowledge to foster this practical wisdom, but does not expect any individual to be infallible in its application. It is possible that by emphasizing the need for practical wisdom in navigating the plethora of conflicting demands that are experienced by many scientists on a daily basis that virtue ethics might present them with a realistic alternative to "falling short of the expected ideal".

The fieldwork discussed in chapter five highlighted the problems arising from imposing role responsibilities and ethical obligations on scientists who conduct research in environments which vary considerably from those used as reference points for the responsibilities. The chapter suggested that the inability to fulfil such responsibilities due to insufficiencies within their research environments was causing considerable ethical distress amongst scientists as well as altering their perceptions of their membership into the international community of research scientists. By and large, the chapter suggested that the distress and dissociation experienced by the scientists was a result of contextually-insensitive role responsibilities and a perpetuating perception of collective responsibility as an aggregate phenomenon in which all scientists needed to "do their bit" (in a specific way).

Within dual-use education – as indeed with any ethics education – the notion of "practical wisdom" thus may play an important role in assisting scientists in negotiating their "webs of commitment". It will potentially prove a particularly important element to emphasise, as the plethora of emerging dual-use regulations, scientific and social sanctions and personal beliefs all present a complicated milieu in which scientists need to conduct themselves. Thus, by explicitly discussing the possibilities of conflicting obligations, it would be possible to emphasise the need for practical wisdom and experience in maintaining ethical behavior. In this way scientists would be encouraged to look beyond submissive "rule following" to see exactly how these rules and obligations shape their daily ethical life.

Instead of presenting role responsibilities or duties to the scientists, using virtue ethics instead could emphasize the acquisition of knowledge that will facilitate the "practical wisdom". This removes the emphasis from the need to fulfil certain pre-defined obligations, and places it instead on developing a discussion as to how the virtues of the practice of science could be best embodied within a specific environment. By placing the emphasis on the scientists obligation to be aware and to utilize that awareness in their daily decisions it is likely that a more comprehensive perception of ethics could be developed – rather than the "tick box" approach which is all too common amongst many scientists.

Nonetheless, despite the utility of the notions of "webs of commitment" and "practical wisdom" in exposing the conflicting demands of research environments to scientists, it must be noted that such an approach can only go so far. As discussed in the fieldwork of chapter five, conducting research in environments that fell short of the global norm caused considerable ethical and emotional distress amongst scientists – sometimes placing on them

unacceptable burdens, challenges or choices. It must therefore be recognised that any increased attention that the regulatory-physical environment gets in ethical discussions should be accompanied by similar attention by governments and funding bodies. In particular, as evidenced by the fieldwork, there is a desperate need to view scientific research more holistically (using, for example the OSM) and to make provisions accordingly. Thus, making addressing systemic issues in scientific research and the absence of core funding priorities within all discussions of the life sciences will be a great contribution towards building a united scientific community.

### 7.3 Good Behaviour Versus Absence of Bad Behaviour

Throughout this thesis I have made reference to the distinction that I perceive between "good behaviour" and the "absence of bad behaviour". In chapter one I explicitly made a difference between what I perceived to be a focus in research ethics on avoiding bad behaviour, and the need to develop good behaviour that was necessary for confronting broad social issues such as dual-use. In particular, in chapter two, I highlighted how difficult it would be to ascertain whether scientists were, in fact, fostering cultures of awareness and responsibility within their laboratories – as well as emphasizing how difficult it would be to develop such cultures.

In attempting to address this issue, I proposed using the concept of "ethical cultures" (borrowed from business ethics) in discussing these issues. "Ethical cultures" can be understood as the situational moderator of the relationship development between the individual's cognitive moral stage and ethical/unethical conduct. In this model it was proposed that "culture" was comprised of the organization's normative structure (norms about what is and is not appropriate behaviour), referent others' behaviour, expectations about obedience to legitimate authority, and the extent to which the organisation encourages individuals to take responsibility for the consequences of their actions (Trevino 1998). Thus, such cultures are comprised of both "formal" (rules, codes, leadership, training etc), and "informal" (peer behaviour and ethical norms) elements which together work to ensure ethical behaviour.

Although a number of different studies (such as IoM 2002) are starting to consider how mentors and institutions can foster research integrity, the majority of them continue to focus on research ethics – and thus the absence of misbehaviour. How responsibility and awareness for broad social issues are fostered within laboratories is, comparatively, rather a neglected topic. It is possible that using the concept of "ethical cultures" within laboratories may assist in developing this under-examined field. Instead of simply expecting PIs to "do a good job raising awareness", such a re-focus would highlight the necessary emphasis on regulations, as well as social and cultural influences which would influence raising awareness.

This section briefly examines the notion of an "ethical cultures" within laboratories in more detail. In particular it questions how and what would be necessary to establish such cultures, suggesting the promotion of a "moral professionalism" to deal with these issues. In considering "moral professionalism" it is possible that virtue ethics may be able to significantly contribute through a better understanding of *eudaimonia*, or "flourishing".

## 7.3.1 <u>Establishing Ethical Cultures in Laboratories and Stimulating Ethical</u> <u>Behaviour</u>

In much dual-use rhetoric, as with many other ethical discussions, there is an implicit assumption that the PI will instil knowledge and ethical awareness in their staff and students. As discussed in chapters four and six, such expectations do not simply require the PI to be on the lookout for misbehaviours and educate their staff about their responsibilities accordingly. Rather, the PI is required not only to endorse the concept of dual-use, but also understand it sufficiently, see value in the controls that are emerging, and develop an understanding as to how dual-use awareness could be established and perpetuated within his or her laboratory.

In isolation, this would appear to be a daunting task – even for the most ethically educated scientist. Understanding how raising such awareness should be undertaken and what outcomes can be expected are extremely nebulous 332

areas. In contrast to research ethics, which promotes a clear set of duties for PIs to prevent misconduct, how to establish a culture of awareness and responsibility within laboratories that includes a sense of global responsibility for broad social issues is particularly difficult to comprehend.

In attempting to confront this difficult problem, it is possible that introducing the concept of an "ethical culture" within laboratories will stimulate discussion on not only preventing misbehaviour but also on fostering good behaviour. Together, these could be linked together under a proposal of developing an understanding of a "moral professionalism" for the life sciences. In contrast to other disciplines, and particularly when considering areas beyond research ethics, discussions on professionalism in science require further attention.

In particular, promoting a broad interpretation of professionalism that will be able to contextualise the "global responsibility" which is key to understanding many broad social issues will be extremely helpful. Furthermore, by viewing (for example) dual-use as an element in a wider responsibility to humanity it is possible that scientists – and PIs in particular – will find it easier to place their commitments in a moral context and transmit them accordingly.

### 7.3.2 *"Flourishing"* in Scientific Research

One of the problems of attempting to understand a unified interpretation of "moral professionalism" in science is that it would of course either run the risk of over-generalising and lapsing into imperialism, or be too context-specific and lose content through relativism. In this, it is possible that virtue ethics may contribute significant. Virtue ethics is a teleological system in which orients the virtues towards a specific end state of *eudaimonia*, or "flourishing" (Pellegrino 2007: 63). Aristotle suggested this state of flourishing is a "good" is that which all men desire which is oriented to the *telos* of the practice being undertaken (Aristotle: 1094a: 1 - 3).

For example, in medicine the *telos* may be considered the welfare of a human being in a particular existential state, in need of a specific kind of help

(Pellegrino 2007: 64). This could be further divided into four different goods: the medical good, the patient's perception of the good, the good for humans, and the spiritual good (Pellegrino 2007: 70 - 71). Thus, to achieve a state of flourishing in medical practice it is important that these different goods be striven for.

MacIntyre's notion of practices further enriches this approach when considering professions. If professions as practices are understood as containing a particular idea of "good" within it, the notion of *eudaimonia* presents a unifying notion by which claims of relativism may be sidestepped. Thus, despite the plethora of manners in which the *telos* of a practice is striven towards, the notion of the good of a practice remains a constant means of initiating cross-cultural dialogue.

Discussions about the *telos* of scientific research, and the state of flourishing that could be reached by correctly applying the virtues identified for research are potentially fruitful areas of discussion. In particular, as the *telos* provides an all-encompassing goal (in comparison to the identification of norms of scientific research), it provides a useful means of providing researchers with a comprehensive picture of the desired outcomes of science and does not provide different (and potentially contradicting) goals that must be met.

In chapter six I examined the establishment of ethical cultures within laboratories. I emphasized that although the social cultures of each fieldsite differed considerably there nonetheless existed a commitment towards ethical behavior in research. I also suggested that current means in which dual-use initiatives emphasize "teaching through example" do not take these ethical cultures into account, instead focusing on a Western interpretation of the social cultures of laboratories.

If dual-use education promoted the notion of ethical cultures, and drew students' attention to the idea of *flourishing* within a specific workplace, it might

facilitate considerable discussion. In particular, it would encourage students to critically assess how the "goods" of science as a practice (the scientific good, the god for humans and the spiritual good) were being striven for in their labs. Furthermore, emphasizing the community's responsibilities towards the development of dual-use aware work environments would promote a general commitment towards moral excellence and caring – all of which re-emphasize the global responsibilities that scientists have with regard to dual-use.

Despite the potential utility of the notion of *eudaimonia*, and ethical cultures for discussions in life science ethics, it must however be noted that understanding *how* ethical cultures may be understood in laboratories, *what* constitutes such a culture and *how* it is perpetuated are all areas which require considerable further examination.

### 7.4 Concluding Remarks

This thesis has hopefully provided some insight into certain problems associated with discussing responsibility in the life sciences. In particular, as demonstrated in chapter one, how the internal responsibilities of research are framed can differ considerably to those relating to the broad social issues of science. Nonetheless, ethics education for scientists tends to rely predominantly on the field of research ethics to introduce both the internal responsibilities and the broad social issues. This, as was suggested, has the potential to cause significant confusion amongst scientific communities.

Using the concept of dual-use as an example of a broad social issue, chapter two critically analysed the effect of using the RCR model to raise awareness of dual-use amongst life science communities. Close inspection of current modes of education suggested that there were some significant issues that might become problematic in education – especially when considering including developing country scientists in dual-use debates.

These issues were subsequently examined empirically in chapters four to six. The fieldwork demonstrated that the theoretical issues identified in chapters one and two did indeed represent some of the problems that scientists had with the current modes of dual-use education. These data strongly suggested that current modes of ethics pedagogy needed to be carefully reexamined and unpacked in order to ameliorate these problem areas.

In this chapter further ways to address these problems were considered in detail. In particular, this chapter suggests that using alternative ethics approaches such as virtue ethics may prove extremely useful in confronting some of these problem areas. Of course, virtue ethics is often criticized for being difficult to teach, and this thesis by no means suggests otherwise. What it does suggest, however, is that key concepts such as "moral communities", "practical wisdom", "flourishing" and "science as a practice" be examined in further detail. It is possible that these concepts will be able to contribute an alternative approach to current ethics teaching – one that promotes the idea of "moral professionalism" within scientific research.

Furthermore, considerable additional data arose from the comparative empirical investigations. The fieldwork strongly demonstrated the limits of assuming homogeneity within the scientific population – both in social cultures, responsibility commitments, and regulatory-physical environments. Although this thesis by no means suggests that the current drive towards international harmonization within science control is anything but very necessary, what the fieldwork does point out is the importance of recognizing these variations between scientific communities. A greater sensitivity to these variations will ensure that a mid-ground is ground is found between an overly imperialistic approach of one which lapses into relativism.

Moreover, and of considerable importance, the fieldwork also suggested that developing cultures of awareness and responsibility within communities of scientists requires a sensitivity to the entire research environment, and not just a section thereof. Thus, when considering raising ethics awareness in laboratories it is necessary to consider the regulatory-physical environment as well as the moral culture of the research group. In this manner, the fieldwork highlights the importance of future initiatives promoting the OSM model of scientific research to ensure that research be looked at holistically – something which will hopefully be translated into policy and funding as well as ethics discussions.

Nonetheless, teaching ethics to scientists will always be a difficult task. Not only are the limits of funding and space in curricula considerable problems, but making ethics topics pertinent and valuable to science students is no mean feat. Despite these difficulties, in an increasingly socially critical age, scientists are going to have to engage not only with their internal responsibilities to their work and colleagues, but also with the broad social issues that arise out of the social contract that science has with society. Thus, finding alternative ways in which to present these subjects to scientists, and to find approaches that allow scientists to see value in these discussions is proving an important part of current life science ethics. By presenting the data in this thesis, it is hoped that this study will contribute towards that laudable goal.

# 8. Bibliography

AAAS (2009). A Survey of Attitudes and Actions on Dual-Use Research in the Life Sciences. Washington D. C., American Association for the Advancement of Science and the National Research Council.

AAAS (2010). Competing Responsibilities: Addressing the Security Risks of Biological Research in Academia. Washington D. C., American Association for the Advancement of Science and Association fo Public and Land-grant Universities.

Altas, R. M., Somerville, M. (2007). Life sciences or death sciences: tipping the balance towards life with ethics, codes and laws. <u>A Web of Prevention</u>. B. Rappert, McLeish, C. London, Earthscan.

Anderson, M. (2007). "Collective openness and other recommendations for the promotion of research integrity." <u>Science and Engineering Ethics</u> **13**: 387 - 394.

Anderson, M. S., Horn, A. S., Risbey, K. R., Ronning, E. A., De Vries, R., Martinson, B. C. (2007). "What do mentoring and training in the responsible conduct of research have to do with scientists' misbehaviour? Findings from a national survey of NIH-funded scientists." <u>Academic Medicine</u> **82**(9): 853 - 860.

Anderson, M. S., Ronning, E. A., de Vries, R., Martinson, B. C. (2007). "The perverse effects of competition on scientists' work and relationships." <u>Science and Engineering</u> <u>Ethics</u> **13**: 437 - 461.

Aristotle The Nicomachean Ethics. Oxford, Oxford University Press.

Arrington, R. L. (1998). <u>Western ethics: an historical introduction</u>. Massachusetts, Blackwell Publishers.

Atlas, R. M., Dando, M. R. (2006). "The dual-use dilemma for the life sciences: perspectices, conundrums, and global solutions." <u>Biosecurity and Bioterrorism:</u> <u>Biodefense Strategy, Practice, and Science</u> **4**(3): 276 - 286.

Atlas, R. M., Dando, M. R. (2006). "The dual-use dilemma for the life sciences: perspectives, conundrums, and global solutions." <u>Biosecurity and Bioterrorism</u> **4**(3): 276 - 286.

Bacon, F., Ed. (1887). <u>The Works</u>. London.

Baggini, J., Fosl, P. S. (2007). <u>The Ethics Toolkit</u>. Oxford, Blackwell Publishing.

Beauchamp, T. L. (1997). "Engelhardt's Foundations." Reason Papers 22: 96 - 100.

Beauchamp, T. L., Childress, J. F. (2001). <u>Principles of Biomedical Ethics</u>. Oxford, Oxford University Press.

Benatar, S. R. (2002). "Reflections and recommendations of research ethics in developing countries." <u>Social Science and Medicine</u> **54**: 1131 - 1141.

Bezuidenhout, L. (2012). "Research infrastructures, policies and the "web of prevention": the ethical implications of inadequate research environments." <u>Medicine,</u> <u>Conflict and Survival</u> **28**(1): 19 - 30.

Bezuidenhout, L., Rappert, B. (2012). The Ethical Issues of Dual-use and the Life Sciences, Collaborative Online Resource Environment. http://nationalethicscenter.org/coreissues.

Braxton, J. M., Bayer, A. E. (1994). "Perceptions of research misconduct and an analysis of their correlates." Journal of Higher Education **65**(3): 351 - 372.

Braxton, J. M., Bayer, A. E. (1996). "Personal experiences of research misconduct and the response of individual academic scientists." <u>Science, Technology and Human</u> <u>Values</u> **21**(2): 198 - 213.

Broad, W., Wade, N. (1983). <u>Betrayers of Truth: Fraud and Deceit in the Halls of Science</u>. London, Cetury Publishing.

Bryant, J., la Velle, L. B. (2003). "A bioethics course for biology and science education students." Journal of Biological Education **37**(2): 91 - 95.

Bryman, A. (2008). Social Research Methods. Oxford, Oxford University Press.

BTWC (1972). The Biological and Toxic Weapons Convention. Geneva.

Castello, M., Botella, L. (2006). Constructivism and educational psychology. <u>The</u> <u>Praeger Handbook of Education and Psychology</u>. J. L. Kinchelow, Horn, R. A. Westport, CT, Praeger.

Cello, J., Paul, A. V., Wimmer, E. (2002). "Chemical synthesis of poliovirus cDNA: generation of an infectious virus in the absence of natural template." <u>Science</u> **9**: 1016 - 1018.

Chambliss, D. F. (1996). <u>Beyond caring: hospitals, nurses, and the social organization</u> <u>of ethics</u>. London, University of Chicago Press.

Cho, M. K., McGee, G., Magnus, D. (2006). "Lessons from the stem cell scandal." <u>Science</u> **311**: 614 - 615.

Christakis, D. A., Feudtner, C. (1993). "Ethics in a short white coat: the ethical dilemmas that medical students confront." <u>Academic Medicine</u> **68**: 249 - 254.

Christakis, N. A. (1992). "Ethics are local: engaging cross-cultural variation in the ethics for clinical research." <u>Social Science and Medicine</u> **35**(9): 1079 - 1091.

Clarke, S. (forthcoming). The precautionary principle and the dual use dilemma. <u>On the Dual Uses of Science and Ethics</u>. B. Rappert, Selgelid, M. Canberra, Australian National University E Press.

Clevestig, P. (2009). <u>Handbook of Applied Biosecurity for Life Science Laboratories</u>. Stockholm.

COHRED (2010). "Fact sheet accompanying report " NEPAD-COHRED Strengthening Pharmaceutical Innovation in Africa"."

COHRED (2010). Fact sheet: NEPAD-COHRED Strengthening Pharmaceutical Innovation in Africa.

Collins, H. M. (1983). "The sociology of scientific knowledge: studies of contemporary science." <u>Annual Review of Sociology</u> **9**: 265 - 285.

COMEST (2003). The Teaching of Ethics. Paris, France, UNESCO.

Dando, M. (2009) Bioethicists enter the dual-use debate. <u>Bulletin of the Atomic Scientists</u>

Dando, M. R., Rappert, B. (2005). <u>Codes of conduct for the life sciences: some insights</u> from UK academia. Bradford, Department of Peace Studies, University of Bradford.

De Vries, R., Anderson, M. S., Martinson, B. C. (2006). "Normal misbehaviour: scientists talk about the ethics of research." <u>Journal of Empirical Research on Human</u> <u>Research Ethics</u> **1**(1): 43 - 50.

Denison, D. (1996). "What is the difference between organizational culture and organizational climate? a native's point of view on a decade of paradigm wars." Academy of Management Review **21**(3): 619 - 654.

Dibetle, M., Mohlala, T. (2010). Budget snubs academics. <u>Mail and Guardian</u> Johannesburg, Anastacia Martin. **22/02/2010**.

Doig, A., Wilson, J. (1998). "The effectiveness of codes of conduct." <u>Journal of</u> <u>Business Ethics</u> **7**(3): 140 - 149.

Donnelley, S. (1989). "Hans Jonas, the philosophy of nature, adn the ethics of responsibility." <u>Social Research</u> **56**(3): 635 - 657.

Douglas, H. (2007). <u>Rejecting the ideal of value-free science</u>. Oxford, Oxford University Press.

Douglas, T. M. (2007). "Ethics committees and the legality of research." <u>Journal of</u> <u>Medical Ethics</u> **33**: 732 - 736.

Editorial (2011). "A helping hand." Nature 474: 542.

Ehni, H. J. (2008). "Dual use and the ethical responsibility of scientists." <u>Arch. Immunol.</u> <u>Ther. Exp</u> **56**: 147 - 152.

Engelhardt, H. T. (2011). "Confronting moral pluralism in posttraditional Western societies: bioethics critically reassessed." <u>Journal of Medicine and Philosophy</u> **36**: 243 - 260.

Engelhardt, H. T. (2012). "Bioethics critically reconsidered: living after foundations." <u>Theroetical Medical Bioethics</u> **33**: 97 - 105.

Engelhardt Jr, H. T. (1985). <u>The Foundations of Bioethics</u>. Oxford, Oxford University Press.

Engelhardt Jr, H. T. (1986). <u>The Foundations of Bioethics</u>. Oxford, Oxford University Press.

Evans, N. G. (2010). Dual-use Bioethics: the Nuclear Connection. <u>Wellcome Trust:</u> <u>Building Sustainable Capacity in Dual-use Bioethics monographs</u>. Bradford, University of Bradford.

Evers, K. (2001). Standards for Ethics and Responsibility in Science: an Analysis and Evaluation of Their Content, Background and Function. Paris, International Council for Science.

Feakes, D., Rappert, B., McLeish, C. (2007). Introduction: a web of prevention? <u>A Web of Prevention</u>. B. Rappert, McLeish, C. London, Earthscan.

Feudtner, C., Christakis, D. A., Christakis, N. A. (1994). "Do clinical clerks suffer ethial erosion? Students' perceptionso f their ethical environment and personal development." <u>Academic Medicine</u> **69**(8): 670 - 679.

Fine, J. C. (2007). Investing in STI in Sub-Saharan Africa: lessons from collaborative initiatives in research and higher education. Washington DC, Global forum: building science, technology and innovation capacity for sustainable growth and poverty reduction.

Fine, J. C. (2007). <u>Investing in STI in Sub-Saharan Africa: lessons from collaborative</u> <u>initiatives in research and higher education</u>. Global forum: building science, technology and innovation capacity for sustainable growth and poverty reduction, Washington DC.

Fink, H. (2003). Hvad er et universitet? <u>Universitet og Videnskab</u>. H. Fink, Kjaergaard, P. C., Kragh, H., Kristensen, J. E. Copenhagen, Hans Reitzels Forlag.

Franzen, M., Rodder, S., Weingart, P. (2007). "Fraud: causes and culprits as perceived by science and the media." <u>EMBO Reports</u> **1**: 3 - 7.

Frey, J. H., S.M.Oishi (1995). <u>How to Conduct Interviews by Telephone and in Person.</u> . London.

Frith, L. (2012). "Symbiotic emprical ethics: a practical methodology." Bioethics **26**(4).

Gibbons, M. (1999). "Science's new social contract with society." <u>Nature</u> **402**(SUPP): C81 - C84.

Gorman, B. J. (2006). "Biosecurity and secrecy policy: problems, theory and a call for executive action." <u>I/S: A Journal of Law and Policy</u> **2:1**: 53 - 102.

Hansen, T. B. (2005). Teaching ethics to science and engineering students: report from a follow-up symposium to the 1999 World conference on Science. Copenhagen, Center for the Philosophy of Nature and Science Studies, University of Copenhagen.

Hansen, T. B. (2006). "Academic and social responsibility of scientists." <u>Journal on</u> <u>Science and World Affairs</u> **2**(2): 71 - 92.

Haraway, D. (1992). "The biopolitics of a multicultural field." <u>GENDAI-SHISO revue de</u> <u>la pensee d'aujourd'hui 20</u> **10**: 108 - 147.

Harris, E. D. (2008). Controlling Dangerous Pathogens: a Proposed International Biosecurity Oversight System. <u>Promoting Biosafety and Biosecurity wtihin the Life Sciences: an International Workshop in East Africa</u>. Kampala, Uganda, Uganda National Academy of Sciences.

Hart, H. L. A. (2008). <u>Punishment and Responsibility: Essays in the Philosophy of Law</u>. Oxford, Oxford University Press.

Hegel, G. W. F. (1952). <u>Hegel's Philosophy of Right</u>. Oxford, Clarendon Press (Trans: T. M. Knox).

Hess, D. J. (1995). <u>Science and Technology in a Multicultural World</u>. New York, Columbia University Press.

Higgs-Kleyn, N., Kapelianis, D. (1998). "The role of professional codes in regulating ethical conduct." Journal of Business Ethics **19**: 363 - 374.

Honderich, T., Ed. (2005). <u>The Oxford Guide: Philosophy</u>. Oxford, Oxford University Press.

Hume, D. (1888). A Treatise on Human Nature. Oxford.

Hundert, E. M., Hafferty, F. W., Christakis, D. (1996). "Characteristics of the informal curriculum and trainees' ethical choices." <u>Academic Medicine</u> **71**(6): 624 - 633.

Hursthouse, E. (2007). Environmental virtue ethics. <u>Working Virtue. Virtue Ethics and</u> <u>Contemporary Moral Problems</u>. R. L. Walker, Ivanhoe, P. J. . New York, Oxford University Press.

Hursthouse, E. (2012). Virtue ethics. <u>Stanford Encylopedia of Philosophy</u>, Zalta, E. N. (ed), Stanford University.

IAP (2005). IAP Statement on Biosecurity. Trieste, InterAcademy Panel.

ICRC (2003). Biotechnology, Weapons and Humanity. Geneva, ICRC.

IoM (2002). Integrity in Scientific Research. Washington D.C., Institute of Medicine and National Research Council.

Irikefe, V., Vaidyanathan, G., Nordling, L., Twahirwa, A., Nakkazi, E., Monastersky, R. (2011). "The view from the front line." <u>Nature</u> **474**: 556 - 559.

Jackson, R. J., Ramsay, A. J., Christensen, C. D., Beaton, S., Hall, D. F., Ramshaw, I. A. (2001). "Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox." Journal of Virology **75**(3): 1205 - 1210.

Jaspers, K. (1961). The question of German guilt. New York, Capricorn.

Jonas, H. (1979). <u>The Imperative of Responsibility: in Search of Ethics for the Technological Age</u>. Chicago, University of Chicago Press.

Jones, N. (2007). "A code of conduct for the life sciences." <u>Science and Engineering</u> <u>Ethics</u> **13**: 25 - 43.

Journal\_Editors\_and\_Authors\_Group (2003). "Uncensored exchange of scientific results." <u>PNAS</u> **100**(4): 1464.

Kahn, M. (2006). Preparations and expectations. Presentation to the United Nations General Assembly First Committee. <u>Sixth Review Conference of the Biological and Toxin Weapons Convention</u>. New York.

Katongole-Mbidde, E. (2008). Promoting Biosafety and Biosecurity Within the Life Sciences. <u>Promoting Biosafety and Biosecurity Within the Life Sciences: an International Workshop in East Africa</u>. Kampala, Uganda, Uganda National Academy of Science.

Kelle, A., Nixdorff, K., Dando, M. (2006). <u>Controlling biochemical weapons</u>. New York, Palgrave Macmillan.

Kellenberger, J. (2002). Biotechnology: an appeal to governments and scientists. International Herald Tribune.

Kenya, E. (2008). Engaging Scientists in Biosecurity: an African Perspective. <u>Promoting Biosafety and Biosecurity Within the Life Sciences: an International</u> <u>Workshop in East Africa</u>. Kampala, Uganda, Uganda National Academy of Sciences.

Kincaid, H., Dupre, J., Wylie, A. (2007). <u>Value-Free Science? Ideals and Illusions</u>. Oxford, Oxford University Press.

Kintisch, E. (2005). "Researcher faces prison for fraud in NIH grant applications and papers." <u>Science</u>: 1851.

Kirigia, J. M., Wambebe, C., Baba-Moussa, A. (2005). "Status of national research bioethics committees in the WHO African region." <u>BMC Medical Ethics</u> **6**(10).

Kitzinger, J. (1994). "The methodology of focus groups." <u>Sociology of Health and Illness</u> **16**(1): 103 - 121.

Kitzinger, J., Barabour, R. (1999). Introduction. <u>Developing focus group reserach</u>. R. Barabour, Kitzinger, J. London, Sage.

Korenman, S. G., Berk, R., Wenger, N. S. et al (1998). "Evaluation of the research norms of scientists and administrators responsible for academic research integrity." JAMA **279**(1): 41 - 47.

Kornfeld, D. S. (2012). "Research misconduct: the search for a remedy." <u>Academic Medicine</u> **87**(7): 877 - 882.

Kuhlau, F., Eriksson, S., Evers, K., Hoglund, A. T. (2008). "Taking due care: moral obligations in dual use research." <u>Bioethics</u> **22**(9): 477 - 487.

Kuhlau, F., Hoglund, A. T., Evers, K., Eriksson, S. (2009). "A precautionary principle for dual use research in the life sciences." <u>Bioethics</u> **25**: 1 - 8.

Kuhn, T. (1962). <u>The structure of scientific revolutions</u>. Chicago, Chicago University Press.

Kumar, M. N. (2010). "A theoretical comparison of the models of prevention of research misconduct." <u>Accountability in Research</u> 17(2): 51 - 66.

Ladd, J. M., Lappe, M. D., McCormick, J. B., Boyce, A. M., Cho, M. K. (2009). "The "how" and "whys" of research: life scientists' views of accountability." <u>Journal of Medical Ethics</u> **35**: 762 - 767.

Latour, B., Woolgar, S. (1986). <u>Laboratory Life: the Construction of Scientific Facts</u>. Princeton, Princeton University Press.

Luegenbiehl, C. (1991). Codes of ethics and the moral education of engineers. <u>Ethical</u> <u>Issues in Engineering</u>. D. Johnson. Saddle River, NJ, Prentice Hall.

MacIntyre, A. (1984). After Virtue. Notre Dame, University of Notre Dame Press.

MacIntyre, A. (1998). <u>A Short History of Ethics</u>. London, Routledge.

Malsch, I. (2009). "Individual and collective responsibility for nanotechnology."

Mancini, G., Revill, J. (2008). Fostering the Biosecurity Norm: Biosecurity Education for the Next Generation. Bradford, UK, University of Bradford.

Martinson, B. C., Anderson, M. S., Crain, A. L., de Vries, R. (2005). "Scientists' perceptions of organizational justice and self-reported misbehaviours." <u>Journal of Empirical Research of Human Research Ethics</u> **1**: 51 - 66.

Masanza, M. M., Nqobile, N., Mukanga, D., Gitta, S. N. (2010). "Laboratory capacity building for the International Health Regulations (IHR[2005]0 in resource-poor countries: the experience of the African Field Epidemiology Network (AFENET)." <u>BMC</u> <u>Public Health</u> **10**(Suppl 1): S8 - S15.

May, L. (1987). The Morality of Groups. Notre Dame, University of Notre Dame Press.

May, L. (1996). <u>The Socially Responsive Self.</u> Social Theory and Professional Ethics. Chicago, University of Chicago Press.

McLeish, C. (2007). Reflecting on the problem of dual use. <u>A Web of Prevention</u>. C. McLeish, Rappert, B. London, Earthscan.

McLeish, C., Nightingale, P. (2007). "Biosecurity, bioterrorism and the governance of science: the increasing convergence of science and security policy "<u>Research Policy</u> **36**: 1635 - 1653.

Merton, R. K. (1973). The Sociology of Science. Chicago, Chicago University Press.

Miller, S. (2001). <u>Social Action: a Teleological Account</u>. Cambridge, Cambridge University Press.

Miller, S., Selgelid, M. J. (2007). "Ethical and philosophical considerations of the dualuse dilemma in the biological sciences." <u>Science and Engineering Ethics</u> **13**: 523 - 580.

Minehata, M. (2010). An Investigation on Biosecurity Education for Life Scientists in the Asia Pacific Region. <u>Research Monograph for the Wellcome Trust project "Building</u> Sustainable Capacity in Dual-Use Bioethics". Bradford, University of Bradford.

Minehata, M., Friedman, D. (2009). Biosecurity Education in Israeli Research Universities: Survey Report. <u>Research Report for the Wellcome Trust Project "Building Sustainable Capacity in Dual-Use Bioethics"</u>. Tel Aviv, The Institute for National Security Studies.

Minehata, M., Shinomiya, N. (2010). Japan: Obstacles, lessons and future. <u>Education</u> <u>and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Warfare</u>. B. Rappert. Canberra, Australian National University Press.

Mitcham, C. (2003). "Co-responsibility for research integrity." <u>Science and Engineering</u> <u>Ethics 9</u>: 273 - 290.

Morgan, D. (1998). Focus groups as qualitative research. London, Sage.

Murenzi, R. (2011). "Give the new generation a chance." Nature 474: 543.

NAS (1992). Responsible Science: Ensuring the Integrity of the Research Process (Volume 1). Washington DC, National Acadmies Press.

NAS (2009). On Being a Scientist: a Guide to Responsible Conduct in Research. Washington DC, National Academies Press.

Nichols, P. (1991). Social Survey Methods. Oxford.

Nordling, L. (2010). Africa analysis: lateral thinking for research funding. <u>SciDev.net</u>. Cape Town, online. **20/04/2010**.

Nordling, L., Ahmed, M. (2010). Ministers promise a decade for African science. <u>SciDev.net</u>. Cape Town, online. **19/03/2010**.

Novossiolova, T. (2011). Dual-use biosecurity education beyond the classroom: continuing professional development for life scientists. Bradford, University of Bradford.

Nowak, R. (2001). "Disaster in the making." New Scientist 2273(13 January).

NRC (2002). Making the Nation Safer: the Role of Science and Technology in Countering Terrorism. Washington D. C., National Research Council.

NRC (2004). Biotechnology Research in an Age of Terrorism. Washington D.C., National Research Council.

NRC (2004). Seeking Security: Pathogens, Open Access and Genome Databases. Washington D.C., National Research Council.

NRC (2009). A Survey of Attitudes and Actions on Dual-Use Reserach in the Life Sciences: a Collaborative Effort of the National Research Council and the American Association for the Advancement of Science. Washington D.C., National Academies Press.

NRC (2011). <u>Challenges and Opportunities for Education about Dual-Use Issues in the Life Sciences</u>. Washington D. C., The National Academies Press.

NSABB (2006). Charter - National Sceince Advisory Board for Biosecurity. Washington DC, The National Academies Press.

NSABB (2006). Globalization, Biosecurity and the Future of the Life Sciences. Washington D. C., The National Academies Press.

NSABB (2007). <u>Proposed framework for the oversight of dual use life sciences</u> research: strategies for minimizing the potential misuse of research information, National Research Council.

Nussbaum, M. C. (1993). Non-relative virtues: an Aristotelian approach. <u>The Quality of Life</u>. M. C. Nussbaum, Sen, A. Oxford, Oxford University Press.

Nyika, A., Kilama, W., Tangwa, G. B., Chilengi, R., Tindana, P. (2009). "Capacity building of ethics review committees across Africa based on the results of a comprehensive needs assessment survey." <u>Developing World Bioethics</u> **9**(3): 149 - 156.

OECD (2007). Best Practice Guidelines on Biosecurity for BRCS, Organization for Economic Cooperation and Development.

Olsson, B. (2009). Donors must fund the essential conditions for research. <u>SciDev.net</u>. Cape Town, online. **11/03/2009**.

Pellegrino, E. D. (2007). Professing medicine, virtue based ethics and the retrieval of professionalism <u>Working Virtue</u>. Virtue Ethics and Contemporary Moral Problems. R. L. Walker, Ivanhoe, P. J. New York, Oxford University Press.

Rappert, B. (2007). <u>Biotechnology, Security and the Search for Limits</u>. New York, Palgrave Macmillan.

Rappert, B. (2007). <u>Biotechnology, Security and the Search for Limits</u>. An Inquiry into <u>Research and Methods</u>. Houndmills, Palgrave MacMillan.

Rappert, B. (2007). "Codes of conduct and biological weapons." <u>Biosecurity and</u> <u>Bioterrorism</u> **5**(2): 145 - 154.

Rappert, B. (2007). Education for the life sciences: choices and challenges. <u>A Web of</u> Prevention. B. Rappert, McLeish, C. London, Earthscan.

Rappert, B., Ed. (2010). <u>Education and Ethics in the Life Sciences</u>. Canberra, Australian National University Press

Rappert, B. (2010). Education as ... <u>Education and Ethics in the Life Sciences:</u> <u>Strengthening the Prohibition of Biological Warfare</u>. B. Rappert. Canberra, Australia, Australian National University Press.

Rappert, B., McLeish, C., Ed. (2007). <u>A Web of Prevention</u>. <u>Biological Weapons, Life</u> <u>Sciences and the Governance of Research</u>. Science in Society Series. London, Earthscan.

Raskin, J. D. (2002). Constructivism in psychology: personal construct psychology, radical constructivism and social constructivism. <u>Studies in Meaning: Exploring</u> <u>Constructivist Psychology</u>. J. D. Raskin, Bridges, S. K. New York, Pace University Press.

Resnik, D. (1998). The Ethics of Science. New York, Routledge.

Resnik, D. B. (2010). "What is ethics in research and why is it important?". Retrieved 07/04/2010, 2010.

Resnik, D. B. (2011) What is ethics in research and why is it important? http://www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

Revill, J. (2009). Biosecurity and Bioethics Education: a Case Study of the UK Context. <u>Research Monograph for the Wellcome Trust Project "Building Sustainable Capacity in</u> <u>Dual-Use Bioethics"</u>. Bradford, University of Bradford.

Rheinberger, H. J. (2010). <u>On historicizing epistemology</u>. <u>An essay</u>. Stanford, Stanford University Press.

Rockwell, S. (2009). "The FDP faculty burden survey." Res Manag Rev 16(2): 29 - 44.

Scholze, S. (2006). "Setting standards for scientists." <u>EMBO Reports</u> **Special Issue**: S65 - S67.

Schrader-Frechette, K. (1994). <u>Ethics of Scientific Research</u>. Boston, Rowman and Littlefield.

SCRES (2001). Standards for ethics and responsibility in science - an empirical study, The Standing Committee for Responsibility and Ethics in Science.

Selgelid, M. J., Weir, L. (2010). "The mousepox experience: an interview with Ronald Jackson and Ian Ramshaw on dual-use research." <u>EMBO Reports</u> **11**(1): 18 - 24.

Sengooba, T. (2008). Developing National Biosafety Systems. <u>Promoting Biosafety</u> and Biosecurity within the Life Sciences: an International Workshop in East Africa. U. N. A. o. Sciences. Kampala, Uganda, Uganda National Academies of Sciences.

Shamoo, A., Resnik, D. (2009). <u>Responsible Conduct of Research</u>. New York, Oxford University Press.

Somerville, M. A., Atlas, R. M. (2005). "Ethics: a weapon to counter bioterrorism." <u>Science</u> **307**: 1181 - 1182.

Steneck, N. H. (2007). Introduction to the Responsible Conduct of Research. Washington DC, Office of Research Integrity.

Stewart, D., Shamdasani, P. (1992). Focus Groups. London, Sage.

Steyn, B. (2008). Biotechnology and Biorisk in Africa. <u>Promoting Biosafety and Biosecurity within the Life Sciences: an International Workshop in East Africa</u>. Kampala, Uganda, Uganda National Academy of Sciences.

Sture, J., Minehata, M. (2010). Dual-use education for life scientists: mapping the current global landscape and developments. <u>Report of the Bradford meeting, July 2010</u>. Bradford, UK, Bradford Disarmament Research Centre.

Swanby, H. (2009). The Revised African Model Law on Biosafety and the African Biosafety Strategy: ACB Briefing Paper 9. Johannesburg, South Africa, African Centre for Biosafety.

Swazey, J., Anderson, M., Lewis, S. (1993). "Ethical problems in academic research." <u>American Scientist</u> **31**: 543 - 553.

Taubenberger, J. K., Ann H. Reid, Krafft, A. E., Bijwaard, K. E., Fanning. T. G. (1997). "Initial Genetic Characterization of the 1918 'Spanish' Influenza Virus." <u>Science</u> **275**(5307): 1793 - 1796.

Traweek, S. (1988). <u>Beamtimes and Lifetimes</u>. Cambridge, Massachusetts, Harvard University Press.

Trevino, L. K. (1986). "Ethical decision-making in organizations: a person-situation interactionist model." <u>Academy of Management Review</u> **11**: 195 - 230.

Trevino, L. K., Butterfield, K. D., McCabe, D. L. (1998). "The ethical context in organizations: influence on employee attitudes and behaviours." <u>Business Ethics</u> Quarterly **8**(3): 447 - 476.

Trevino, L. K., Youngblood, S. A. (1990). "Bad apples in bad barrels: a causal analysis of ethical decision-making behaviour." Journal of Applied Psychology **75**: 378 - 385.

UN (1948). Universal Declaration of Human Rights. Geneva, United Nations.

UN (2008). Report of the Meeting of States Parties, BWC/MSP/2008/5. Geneva, United Nations

UNAS (2008). Promoting Biosafety and Biosecurity within the Life Sciences: an International Workshop in East Africa. Kampala, Uganda, Uganda National Academy of Sciences.

UNESCO "Code of conduct social science research."

UNESCO (2008). Bioethics Core Curriculum.

UNESCO, I. (1999). Declaration on Science and the Use of Scientific Knowledge. Budapest, World Conference on Science.

van Aken, J. (2006). "When risk outweighs benefit: dual-use research needs a scientifically sound risk-benefit analysis and legally binding biosecurity measures." <u>EMBO reports</u> **7**(special issue): S10 - S13.

Venter, A. J. (2012). <u>How South Africa Built Six Atom Bombs and Then Abandoned Its</u> <u>Nuclear Weapons Program</u>. Johannesburg, Ashanti Publishing.

Victor, B., Cullen, J. B. (1987). A theory and measure of ethical climate in organizations. <u>Research in Corporate Social Performance and Policy</u>. W. C. Frederick. Greenwich, CT, JAI Press.

Walker, R. L., Ivanhoe, P. J. (2007). Introduction. <u>Working Virtue. Virtue Ethics and</u> <u>Contemporary Moral Problems</u>. R. L. Walker, Ivanhoe, P. J. New York, Oxford University Press.

WHO (2004). Laboratory Biosafety Manual. Geneva, World Health Organisation.

WHO (2007). Scientific Working Group on Life Science Research and Global Health Security: Report of the First Meeting. Geneva, World Health Organization.

WHO (2011). Responsible Life Sciences Research for Global Health Security: Part 2. World Health Organisation. Geneva.

WHO/AFRO (1998). Report of the eighteenth meeting of the African Advisory Committee for Health Research and Development. Harare, World Health Organization.

Wocial, L. D. (1995). "The role of mentors in promoting integrity and preventing scientific misconduct in nursing research." <u>Journal of Professional Nursing</u> **11**(5): 276 - 280.

Wright, D. E., Titus, S. L., Cornelison, J. B. (2008). "Mentoring and research misconduct: an analysis of research mentoring in closed ORI cases." <u>Science and Engineering Ethics</u> **14**: 323 - 336.

# **Appendices**

### **Appendix 1: University of Exeter Ethics Approval**



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#### CERTIFICATE OF ETHICAL APPROVAL **College of Social Sciences and International Studies**

School/Academic Unit; Department of Sociology and Philosophy

Title of Project: Dual-use issues changing scientific cultures: an investigation

Name(s)/Title of Project Research Team Member(s): Louise Bezuidenhout

Project Contact Point; Email: Imb214@exoter.ac.uk

Brief Description of Project: This project investigates the understanding of "dual-use issues" by life scientists in the UK, South Africa, Uganda and Kenya.

This project has been approved for the period From: February 2010 To: June 2012

School Ethics Committee approval reference: 23.02.10/viii Amendment approved 01.02.11

<sup>th</sup> Feb. '11 Signature....1.2.4. -<u>A.</u> I. ..... Datc....! (Hannah Farrimond - Chair SSIS School Ethics Committee)

## **Appendix 2: Project Information Sheet**

#### Participant Information Sheet

This information sheet provides background on the aims and methods of our research project and tells you about how the research data will be handled. Before you decide whether you would like to participate in this study, please read the information sheet carefully. If there is anything that you do not understand or if you would like any further information, please contact:

Dr. Louise Bezuidenhout, Department of Sociology in the School of Humanities and Social Sciences, University of Exeter, Byrne House, St. Germans Road, Exeter, EX4 4PJ. UK. Email: <u>Imb214@exeter.ac.uk</u>, Phone: +447500512968

#### What is the purpose of the study?

This project investigates the understanding of "dual-use issues" by life scientists in the UK, South Africa, Uganda and Kenya. The concept of dual-use is centred on the notion that all scientific research could potentially be misused by a third party for malicious ends. The concept of dual-use originates in the discussion of biosecurity and bioterrorism, although extends these concepts to include the notion of responsibility in science and the ethics of scientific research.

Debates on dual-use issues, and matters of dual-use regulation and control are becoming increasingly important to the development of a responsible scientific culture and aspects of the dual-use debate have the potential for far-reaching implications such as altering funding structures, access to resources and publication of data. It is therefore of vital importance that dual-use awareness be raised amongst scientific communities.

The research in which you will be participating forms the basis for a PhD which examines dualuse awareness and understanding amongst scientific populations in the developed and developing world, and the manner in which the concept of dual-use and associated concept s such as scientific responsibility are discussed in the different contexts.

#### What methods do we use?

This project will use a combination of quantitative data gathering methods. These include focus groups and interviews. Both consist of semi-structured discussion on the topic of dual-use.

#### Confidentiality

All data will be treated as strictly confidential unless disclosure is required by a court order. Tapes, electronic files, transcripts and notes will be stored securely at the University of Exeter. They will not be used other than for the purpose of this study and will only be accessible to the research team. Quotes from the interview data may be used in presentations or publications, but they will not disclose the identity of the participants.

#### Participation in the study

The participation in this study is voluntary and participants are free to withdraw from the study at any time.

#### What will happen with the results of this study?

The results of this study will form the basis of presentations and publications in the field of social science. Data obtained from this study will be kept in a secure location for the duration of the analyses after which it will be destroyed.

# Appendix 3: Informed Consent Form

#### **Consent Form for Participants**

Please tick the boxes, fill in the lines below and sign the form. Thank you for your help!

Please note that this consent form is accompanied by an information sheet detailing the nature of this project.

- □ I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions about participating in the research.
- My questions concerning participation in this study have been answered by Dr Bezuidenhout to my satisfaction
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.
- I agree to take part in the research and to the use of my data for the purposes of the study specified in the information sheet.
- I agree to my participation being recorded and understand that the data will be kept securely and will remain confidential except in the case of legal subpoena.
- Should any quotes be used, I will not be identified in any subsequent transcription or publication unless I indicate otherwise.

Name of Interviewee :	
Institute:	
Contact Email:	
Date:	
Signature:	

Project Contact Details: Dr Louise Bezuidenhout (PhD candidate) lmb214@exeter.ac.uk University of Exeter, Byrne House, St. Germans Road, Exeter, EX4 4PJ, UK

# **Appendix 5: Focus Group Information Sheet**

### **Dual-use Focus Group Information Sheet**

#### Background

Dual-use is a concept that is becoming increasingly important to discussions about the lifesciences. In a general sense it is taken to mean the potential for well-intentioned, beneficial research to be misused in the future by a third party for malicious means. In recent years (especially since 2001) there has been a rising interest in biosecurity issues, and dual-use is central to discussions about the future potential for beneficial scientific research to be misused

Currently, attempts to control the dual-use potential of the life sciences lack international consensus and the implementation of controls remains very much on an institutional or national level. However, there has been widespread endorsement of the idea of creating a culture of awareness and responsibility in life scientists through increased ethics education and the development of codes of conduct. It is hoped that by sensitizing scientists to dual-use issues will empower the scientific community to develop certain "bottom-up" initiatives that will contribute towards dual-use control.

#### Focus Group Aims and Structure

The Wellcome Trust has recently designated dual-use as an "area of special interest" and has funded a joint project between the Universities of Exeter, Bath, and Bradford and the Australian National University entitled "Building sustainable capacity in dual-use bioethics". The research being done at your institute forms part of my PhD thesis that forms part of this greater project. My particular area of interest is how scientists in developing countries interact with the dual-use debate and their responses to dual-use dilemmas.

Before the focus group I invite you to read through an article published in the Scientific American by Jeffrey Taubenberger et al in which they describe their research on the 1918 Spanish Flu virus. The focus group will take roughly an hour and you will be asked to comment on your impressions on the paper and the issues it raises.

**Capturing a Killer Flu Virus**: Jeffery K. Taubenberger, Ann H. Reid and Thomas G. Fanning

http://www.scientificamerican.com/article.cfm?id=capturing-a-killer-flu-virus

Time permitting, there will also be a chance to discuss dual-use in more broad terms at the end of the focus group.

#### Data Security

The focus group will be recorded and the electronic file stored in a password-protected database. Relevant parts of the focus group will be transcribed and stored as above. The focus group and associated data will be deleted after use by the interviewer and will not be distributed to third parties. Any data used in reports, publications or presentations will be anonymised.