

The roles of codes of conduct in preventing the misuse of scientific research

Summary

Codes of conduct can help to reduce the risk that scientific research will be misused. The process of producing codes raises awareness amongst the target groups and fosters discussion on the potential for misuse. The process of defining the code should include extensive consultation with the target groups to ensure that it is workable; it should also increase the number of individuals aware of the issues of concern. Having a code provides a valuable educational tool for training students and employees about the issues covered.

It is extremely difficult to list the guiding principles (or codes of ethics) that underpin all scientific work without producing bland and generic statements. However, there are clear benefits in producing more detailed codes of practice or conduct that concentrate on a specific area of research and target audience. The World Health Organisation laboratory biosafety manual is a good example of such a document.

Many valuable guidelines and principles for the professional conduct of scientists already exist at organisational, national and international level. These can be adapted for the purpose of preventing the misuse of scientific research. Existing guidelines and principles should be used as the basis for any codes where possible, rather than starting from first principles. Introducing extended codes of conduct or practice based on existing health and safety regulations provides an opportunity for education and training to reinforce these regulations. Such a code would need to be consulted before any new work was conducted and at key stages during the project. This type of code has more value than one that would be consulted only on one occasion, such as during training on joining an organisation or when signing a contract of employment.

1 Introduction

The threat of scientific and technological developments being used for destructive purposes, such as the development of novel biological weapons, is a real one. The scientific community faces the challenge of identifying measures that can be taken to reduce this risk without jeopardising the enormous potential benefits from research advances. This paper outlines the Royal Society's position on the roles of codes of conduct in preventing the misuse of scientific research, building on the Society's previous publications on the subject (Royal Society 2002, 2003 & 2004). Other aspects of scientific conduct, such as scientific fraud and the public responsibilities of scientists, are not addressed in this paper. This paper also discusses methods that complement codes of conduct in preventing the misuse of science, including training and extending existing regulations.

[The current paper has been produced by the Society's committee on the Scientific Aspects of International Security and has been approved by the Council of the Royal Society.]

In October 2004 the Society jointly held a meeting with the Wellcome Trust entitled *Do no harm: reducing* the potential for the misuse of life science research. The meeting bought together academics, Government and industry scientists, representatives of funding bodies and learned societies, scientific publishers, scientific

journalists, Government policy makers and other interested individuals to discuss these issues. The report of the meeting (Royal Society – Wellcome Trust 2004) helped to develop the Society's position on the misuse of life science research.

All types of codes seek to influence behaviour. There are several types of codes that have different aims and methods of implementation. The names used by different organisations to describe the types of codes are not used consistently. Codes can be categorised into three types: codes of ethics, codes of conduct and codes of practice (Rappert 2004). Codes of ethics are concerned with describing personal and professional standards to be upheld; codes of conduct provide guidelines on appropriate behaviour; and codes of practice codify acceptable practice to be enforced. However, it should be noted that some codes contain elements of two or more of these types of codes. In this paper, the term 'code' will be used to describe any code that contains elements of codes of ethics, practice and conduct. When referring to a specific type of code, this paper uses the definitions given above.

There are many examples of codes of conduct that have been in existence for a long time (eg UK Institution of Electrical Engineers since 1972, American Society of Microbiology since 1988 and American Chemical Society since 1965) or have been produced recently (UK Institute of Biology 2005), and a number of organisations, including UNESCO, are currently working on producing a code of conduct. A number of papers have been produced that give extensive background on the history and content of different types of codes (Rappert 2004) and suggestions for practical approaches relating to codes of conduct for the life sciences (Pearson 2005).

The content, promulgation and adoption of codes of conduct for scientists will be discussed at the June 2005 Meeting of Experts in preparation for the December 2005 Annual Meeting of States Parties to the Biological and Toxin Weapons Convention (BTWC). The Society has produced a separate paper on the issues to be discussed at the Meeting of Experts (Royal Society 2005).

2 Producing and implementing codes of conduct

We believe that both the processes involved in producing codes, and codes themselves, have value. Producing codes of any kind raises awareness amongst the target groups and foster discussion on the potential for misuse of life science research and related regulation and legislation. The process of defining the code should include extensive consultation with the target groups to ensure that it is workable; it should also increase the number of individuals aware of the issues of concern. Having a code provides a valuable educational tool for training students and employees about the issues covered. It is vital to determine how to bring any new code to the attention of its target audience and implement it.

It is extremely difficult to list the guiding principles (or code of ethics) that underpin all scientific work without producing bland and generic statements. However, there are clear benefits in producing more detailed codes of practice or conduct that concentrate on a specific area of research and target audience, such as the World Health Organisation laboratory biosafety manual (WHO 2004).

3 Using codes of conduct in training and education

We believe that codes of conduct have considerable value as educational, and as awareness-raising, tools to ensure that scientists are reminded of their legal and ethical responsibilities and that they consider the potential consequences of their research. Undergraduate and postgraduate education programmes should ensure that students are capable of considering the reasonably foreseeable consequences of their activities, which include identification of the possible misuse of science in addition to the tangible benefits that may arise to humanity. These programmes should recognise the potential for later misuse by the trained person of basic skills, technologies or knowledge acquired during the training. Examples of previous misuse of such training could be used where appropriate for the students concerned. When students enter postgraduate training within a research laboratory they are required to read, understand and comply with local and national safety legislation. Codes of conduct or practice would provide an opportunity for education and training to reinforce the ethical and practical aspects of preventing the misuse of science.

The Royal Society and Royal Academy of Engineering (RS-RAEng 2004) recommended that the consideration of ethical and social implications of advanced technologies (such as nanotechnology) should form part of the formal training of all research students and staff.

4 Codes building on existing regulation and legislation

Many valuable guidelines and principles for the professional conduct of scientists already exist at organisational, national and international level. These could be extended for the purpose of preventing the misuse of scientific research. Existing guidelines and principles should be used as the basis for any codes where possible, rather than starting from first principles. It has been suggested that the requirements of the risk assessment process included in the health and safety regulations could be widened slightly to ensure that the proposed activity does not present a risk to the prohibitions enshrined in the BTWC (Pearson 2005). Introducing extended codes of conduct or practice based on existing health and safety regulations provides an opportunity for education and training to reinforce these regulations. Such codes would need to be consulted before any new work was conducted and at key stages during the project. This type of code has more value than one that would be consulted only on one occasion, such as during training on joining an organisation or when signing a contract of employment.

In the UK there is already stringent regulation of all laboratory based work with micro organisms, genetic manipulation of micro organisms and work involving animals. These regulations protect those conducting the experiments and others around them from risks to health, as well as the environment from risks to health. A scientist taking up employment at a UK university has to sign a contract confirming compliance with all local and national safety legislation. Breach of this contract is a dismissible offence. Individual researchers might not be aware of the detail of the legislation that applies to their work, but they will know the procedures required to undertake work with micro organisms, genetic manipulation of micro organisms or work involving animals.

For example, every micro organism or biological agent is classified according to its risk (levels 1-4), with each level having specified conditions for work. All projects must include a risk assessment and be approved by a local safety committee before any work can be undertaken. For higher levels of work approval from the national health and safety authorities is required before work can be started. The UK Health and Safety

Executive regulates all work involving genetic modification and operates the Control of Substances Hazardous to Health (COSHH) regulations.

In addition to safety regulation UK researchers must also comply with the 2001 Anti-terrorism, Crime and Security Act. Managers of laboratories with stocks of specified micro-organisms and toxins must notify the police of their holdings and comply with any reasonable security requirements that the police might request. The police can also ask for details of people who have access to dangerous substances held in labs. The Home Secretary can also prevent named individuals having access to disease strains.

The level of safety regulation varies between nation states, so all nations should be encouraged to have a reasonable level of safety regulation to ensure harmonisation. A possible set of minimum safety requirements are described in the WHO laboratory biosafety manual (WHO 2004). International harmonisation would also make it harder for a scientist to undertake an unsafe activity by simply moving from one country to another.

5 Assessing the risks and benefits of research with the potential for misuse

Most safety regulations involve weighing the potential benefits against any potential risks. This approach is highly applicable to scientific research that has the potential to be applied in both a constructive and destructive way, which is work that can be considered to have a 'dual use'.

The potential risks and benefits should be taken into account when determining whether a particular experiment should be undertaken. This will include assessing the potential for the misuse alongside the proposed increase in scientific understanding or the production of a useful product. Whether the work will generate information with the potential to be misused or produce a dangerous product also needs to be considered. Finally, it is essential that appropriate measures will be taken to ensure that the work will be undertaken safely. All of these considerations need to be taken into account in the risk assessment, making it a complicated balance of probabilities. For example, the work should be prohibited if there seems to be a prospect of making only a dangerous product with no increase in scientific knowledge. In this case the high risk would outweigh the minimal benefits.

How novel the proposed work is should be considered when assessing the risks. If a proposed activity repeats previously published work it does not pose a significant risk relating to the information that might be generated. However, the nature of any physical products of the proposed work would need to be considered. There are two recent examples of publications which can be considered to be contentious in that they unnecessarily may have enabled others to misuse the science involved. In the first of these Jackson et al (2001) demonstrated how to increase virulence of a viral gene (IL-4). A paper that adequately describes the expression of this gene without changing its virulence had been published in 1982 (Panicali & Paoletti 1982). In the second (Cello et al 2002) the regeneration of infectious polio virus from non-infectious synthetic DNA was described. The reconstruction had been reported previously, and in a less politically sensitive time, in 1981 (Racaniello 1981).

The future benefits of work will not always be clear at the time of the experiment, so benefits must be estimated along with any associated risks. For example, the 1982 work on recombinant poxviruses (Panicali & Paoletti 1982) has been used to develop new candidate vaccines against a wide range of infectious diseases and cancers. However, before the experiments were undertaken, published and considered by the wider scientific community it was difficult to say what the tangible benefits of the work would turn out to be.

Part of the assessment of whether a proposed experiment should be conducted involves determination of whether the work can be undertaken safely. There has been considerable concern expressed about the genetic manipulation of influenza virus. This was designed to express selected genes from the 1918 pandemic strain of influenza virus but the work was carried out under containment level 3 rather than the highest level 4 containment (Kawaoka et al 2004). It has been suggested that the risk assessment did not have adequate provision for dealing with an accidental release. If the experiment had been undertaken in a category 4 containment facility any organisms produced would have been destroyed after the work was completed to prevent any risk of release, as is standard practice for level 4 work.

There are likely to be very few experiments undertaken that will pose a significant dual use concern. This was illustrated when the American Society for Microbiology (ASM) introduced formal processes as part of the peer review process for its eleven journals for manuscripts dealing primarily, but not exclusively, with research conducted on select agents. In 2002, 313 select agents manuscripts received special screening from 13,929 manuscripts submitted. Only two of the manuscripts receiving special screening were sent to the full ASM publications board for further screening. Between January and July 2003, of the 8557 manuscripts submitted only 262 select agents manuscripts were screened and none were referred to the publications board for further review (National Research Council 2004). Looking at the number of publications of potential concern gives only part of the total picture as it does not represent all experiments that take place. However, publications are an indicator of the overall picture, and are a good measure of successful work undertaken as work submitted for publication reflects the most successful parts of a researchers' endeavours.

6 Building a web of prevention

Codes of conduct can help to reduce misuse of scientific research. In the UK a series of checks and balances exist at the different stages of the work to reduce the possibility of the misuse of scientific research.

Collectively these steps create a web of prevention. However, the degree to which each of these steps is implemented in practice will vary. First, a scientist requesting funds from a funding agency has to explain the benefit of their application. Referees and review panels should reject grant applications where the potential risks outweighs the potential benefits. Second, if the work is funded, there must be a risk assessment by local (and sometimes national) safety committees before any experiments can take place. Third, if research results are submitted for publication to a journal, the referees and editors should consider if the results have a possible dual use. In very rare cases it might be necessary to insist on appropriate modification before publication or in even rarer circumstances reject the manuscript. Some UK and US academic publishers have guidelines on dual use issues for authors, editors and peer-reviewers (for example UK Society for General Microbiology 2005 and American Society for Microbiology 2005).

The different parts of this web could be strengthened in a number of ways. For example the funding bodies the Wellcome Trust, UK Medical Research Council (MRC) and Biotechnology and Biological Sciences Research Council (BBSRC) undertook a consultation in 2004 on managing the risks of harmful misuse associated with grant funding activities. The three organisations are due to publish a joint statement in 2005 outlining changes to their grant awarding processes based on the consultation results. Also, producing guidance for referees on dual use issues would be helpful, to help referees take them into consideration when assessing both funding proposals and publications.

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