

Averting the hostile use of biomedical research

Current proposals aren't good enough, say Edward Hammond and Jan van Aken

Rapid developments in biotechnology, genetics and genomics open up tremendous possibilities for biological warfare. The Royal Society¹ and the US National Academy of Sciences² have recently proposed a vetting process for research projects before they are undertaken. The US approach, however, falls far short of the minimum requirements for a comprehensive arms control system. It is disturbing to see that the Royal Society also appears to favour some of the unsatisfactory features proposed by the US.

Experiments such as the development of more lethal mousepox strains³, the chemical synthesis of polioviruses⁴ or the partial recreation of the Spanish Flu virus⁵ emphasize the increasing need to control some specific experiments.

Five elements are key to ensuring that experiments, where the potential harm outweighs the potential benefit, are identified and stopped before they begin.

Legally binding

Scientists tend to favour non-binding systems based on their own – individual or collective – responsibility. Anthony Fauci, head of the US National Institute of Allergy and Infectious Diseases, put it bluntly when he said: “*The goal is not to regulate*”.⁶ But it is very doubtful that a responsibility-based system will be comprehensive and effective.

We are currently conducting a survey of nearly 400 Institutional Biosafety Committees (IBC) which are responsible for reviewing the risks of genetic engineering. These are the same committees that, under the US proposals, would perform biosecurity peer review. Initial results indicate that the IBC system is not functioning properly. Even at major research institutions, committee meetings are rare events, risky experiments have been approved without full committee review, and committees often don't meet basic composition and disclosure requirements of the non-binding guidelines under which they are set up.

All inclusive

Every single entity that performs biological/medical research must be covered by the vetting system, including industry, private non-profit institutions as well as military installations. The current exclusion of classified research from the US system appears to be particularly ill-conceived, as this is likely to be the area where most dual-use experiments are to be expected. Large parts of private industry and private non-profits labs in the US, including major biodefence contractors, do not even have IBCs that are registered under the guidelines. If certain types of government funding is the only leverage to enforce compliance, private institutions will not be covered.

¹ Royal Society (2004) The individual and collective role scientists can play in strengthening international treaties. www.royalsoc.ac.uk/policy/

² Biotechnology research in an age of terrorism: confronting the dual use dilemma. www.nap.edu

³ Jackson RJ, Ramsay AJ, Christensen CD, Beaton S, Hall DF, Ramshaw IA (2001) Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox. *J Virol* 75:1205-1210

⁴ Cello J, Paul AV, Wimmer E (2002) Chemical synthesis of poliovirus cDNA: generation of infectious virus in the absence of natural template. *Science* 297:1016-1018

⁵ Tumpey TM, Garcia-Sastre A, Mikulasova A, Taubenberger JK, Swayne DE, Palese P, Basler CF (2002) Existing antivirals are effective against influenza viruses with genes from the 1918 pandemic virus. *PNAS* 99:13849-13854

⁶ US agencies unveil plan for biosecurity peer review. *Science* 303:1595, 12.3.2004

It might be a good idea, though, to demand that grant applications discuss potential biosecurity implications of proposed experiments.

While this may have only limited practical impact, it would greatly contribute to awareness-building in the scientific community.

Transparency

Transparency is a key element of international arms control. Only full transparency in all aspects of biodefence and relevant biological research will enable nations to make a better assessment of others' intentions, and act to discourage suspicion and build good will.

Transparency will also encourage necessary self-restraint among biodefence scientists. If scientists had already been obliged to explain their projects and decisions to a wider audience, some particularly disturbing experiments (such as the deliberate creation of more lethal orthopox viruses by scientists at St. Louis University, USA), would probably have been stopped early on.

Broad representation

A much favoured term these days is the 'bottom-up approach', meaning that scientists should be tasked to operate such an oversight system. While it is certainly desirable to have some scientists with the relevant technical knowledge, we think it is paramount to have a majority of non-scientists on the review board.

Scientists tend to be strongly biased towards 'freedom of science', even in an era in which we must limit certain types of dangerous / provocative research. Security concerns are usually very low on scientists' radar screens. A broad representation of individuals from science, civil society, governmental regulatory agencies and security agencies will ensure a more balanced view of experiments of concern. Many individuals from civil society (non-governmental organisations, neighbourhood committees) and government regulators do have a solid scientific plus a security / arms control background – a fact that is often ignored in the scientific community.

International harmonisation

The microbiological research community is a global one, and a lack of international harmonization of biosecurity/biosafety measures will create security gaps. In order to avoid research tourism, an international standard-setting body should be responsible for defining experiments of concern, and for establishing safety and security requirements for research requiring biological containment.

Whatever a final national or international system may look like, the proposed US guidelines for 'biosafety' and 'biosecurity' appear to be the worst templates. The Royal Society appears to favour a vetting process 'on a case by case basis by the relevant sponsors'⁷, which appears to indicate a non-binding and non-comprehensive system similar to the US.

In autumn 2004, the Royal Society will hold a meeting on biosecurity and bioterrorism. The British scientific community could use this opportunity to endorse mechanisms that go beyond the notion of 'scientific freedom first', that can truly contribute to international arms control.

7. Royal Society (2004) The individual and collective role scientists can play in strengthening international treaties. Page 3, www.royalsoc.ac.uk/policy/