BMA House, Tavistock Square, London, WC1H 9JP
T 020 7383 6755
E cwood@bma.org.uk

Science & Education

15 June 2011

Consultation on emerging biotechnologies

Thank you for inviting the British Medical Association (BMA) to comment on the Nuffield Council on Bioethics' consultation on emerging biotechnologies. The BMA has a long history considering the medical and ethical aspects of developing biotechnologies, in particular in relation to genetic technology and biological weapons. We have published a number of reports in this area, including *The use of drugs as weapons* (2007)[1], *Population and genetic screening* (2005)[2], two volumes entitled *Biotechnology, weapons and humanity* (1999, 2004)[3,4], *Human genetics: choice and responsibility* (1998)[5], and *Medical implications of biological and chemical warfare* (1987)[6]. The BMA is also currently updating its handbook of ethics and law, *Medical ethics today*, [7] and its 1990 report, *Living with risk*. [8]

The BMA welcomes this consultation and its focus on the ethical issues posed by emerging technologies. We provide advice and guidance on a wide range of ethical issues related to medicine and health, based on the knowledge gained through contact with our members and the intellectual rigour provided by the experts in medicine, law, philosophy, ethics and theology who make up our Medical Ethics Committee. We see our role as identifying new and emerging ethical dilemmas and providing robust guidance and direction, as well as encouraging and facilitating informed debate.

The BMA is one of a number of organisations engaged in debate on the ethical and practical issues around emerging technologies, including questions about how to prevent misuse without foregoing any beneficial application or limiting scientific progress. This is becoming increasingly important with the unprecedented pace of technological and scientific development. The past ten years have witnessed rapid advances in genome sequencing, synthetic biology, nanotechnology, and bioinformatics. Consideration of such developments is complicated by the inevitable uncertainties both in the level and scope of risk and the nature of likely future applications.

Our responses to the specific areas covered in the consultation for which there is existing BMA policy are as follows.

11. What ethical principles should be taken into account when considering emerging biotechnologies? Are any of these specific to emerging biotechnologies? Which are the most important?

In relation to emerging technologies, the main focus of concern is the balance of benefits and harms. The risk of harm needs to be considered on various levels incorporating both individual or personal risk and broader risk to society. It needs to incorporate social as well as physical risk and to assess both the likelihood of harm occurring and the level of the harm that could result. A 'serious harm' could involve a significant risk of moderate harm or a small risk of a very serious harm; both would be matters that need to be taken seriously. In any new technology there are uncertainties and a decision needs to be taken about whether, and if so at what stage, to move from research to application. The level of risk and uncertainty that is acceptable will depend upon what is at stake – the likely benefits. With human reproductive cloning, for example, even if the broader ethical issues were resolved, there will always be residual safety concerns which are unlikely to be outweighed by any potential benefit. With gene therapy, whilst there are also likely to be inherent risks, the benefits of providing treatment for very serious conditions, such as cystic fibrosis, are high and could justify a higher level of risk.

Another relevant factor is who would, or might, be harmed. Once research has reached the stage at which safety and efficacy have been assessed, it is for individuals to decide whether to take the risk of participation in, for example, a clinical trial. If a patient with cystic fibrosis has capacity and has been informed that gene therapy is a novel procedure and carries some level of risk it is for that person, as the one affected, to decide whether that risk is worth taking. The situation is very different when the risks affect others, who have not consented, or potentially present a public health risk. This is the case with xenotransplantation where the risks are not restricted to the individual, who would give consent, but also, potentially, to people who come into contact with those individuals, raising very serious issues of public health.

Any suggested benefits of an emerging technology need to be balanced against the potential for significant risk to the general population. Policy and planning should be based on as much evidence as possible (recognising, as mentioned above, that with any new technology there will be considerable areas of uncertainty). With technologies such as genetically modified food, there is a need for further research, but current evidence suggests that risks to public health are unlikely. The BMA has argued that the growth of genetically modified food should not be limited once its safety and benefit has been proven[9]. Recognising that the use of biological agents is illegal, governments needing to protect their population against illegal use must plan to manage this. That plan should include making such a use less feasible as well as actions to limit the harm if use is not averted.

Whilst the balance of benefits and harms is central to all consideration of new and emerging biotechnologies, other ethical principles will come to the fore in discussion on particular issues. Issues of justice and fairness are central to debates on enhancement therapies[10] and questions about human dignity and respect for persons have characterised much of the debate on human embryo research and the use of human admixed embryos.

12. Who should bear responsibility for decision making at each stage of the development of an emerging biotechnology? Is there a clear chain of accountability if a risk of adverse effects is realised?

The presence of national regulatory bodies can allow effective public involvement, build trust, and allow research into new technologies to advance whilst maintaining engagement and scrutiny. The Human Fertilisation and Embryology Authority (HFEA) provides an example of the way this has worked in practice. Responsibility for decisions in this sensitive area ultimately rests with the UK Government and Parliament, but the HFEA has played an important role in building and maintaining public confidence.

The fact that the UK has an effective and trusted regulatory body has made the introduction of new technologies, such as stem cell research and the use of human admixed embryos, much easier. This may, in part, explain why the public response to stem cell research was more positive than that to genetically modified foods. The HFEA has also acted as a conduit for the provision of information and for bringing together interested parties to debate the issues and to reach a broad consensus. The BMA is very concerned that public confidence in this sensitive area could be lost if the Government's plans to abolish the HFEA are followed through.

The 2004 Board of Science report, *Biotechnology, weapons and humanity II*, highlights that scientists have a responsibility for the impact of their work. They must be aware of the risks, ensure they fit within legal and ethical norms, question the potential impacts of publications or projects, and work as a community to police themselves. Responsibility for restricting the development of research that could lead to biological weapons ultimately falls on the international community of nations, in particular the United Nations. Responsibilities also fall on nation states, the academic and medical communities, and individual citizens: 'Governments must engage in debate with scientists, other experts and journal editors about the control of biological experimentation and the dissemination of the results of such research' 'citizens and those with special expertise have a responsibility to contribute to the debate'[11].

Early in the development of a new technology, officials at a national level may not have become aware of its potential. The academic and medical communities must self monitor as research into new technologies develops. This includes the editorial boards of journals and the staff of academic and medical departments, as well as scientists and others involved in research. They should be aware of risks and be active in contributing to debate, with government and the wider public. Once the potential impacts and uses of a certain technology have emerged, responsibility lies with national governments and the international community.

13. What roles have 'risk' and 'precaution' played in policy decisions concerning emerging biotechnologies?

As noted in our response to question 11, risk is central to the challenges of dealing with emerging technologies. Any evaluation of risk or decisions to take precautionary measures must be based on the best available evidence. Good information is not always available, and so a balance must be found between the risks of harm from action, and the risks of harm from non-action. This relates to the concept of the precautionary principle; where there is a high level of uncertainty surrounding risk cause, escalation or consequence, it is prudent to attempt to minimise the potential for harm, without making decisions that are irreversible.

This concept was developed in the 1970s in response to emerging environmental risks such as acid rain, pollution in the North Sea, and climate change. *Biotechnology, weapons and humanity II* highlights that while 'it is clearly impossible to cover all possible biological weaponry attacks that might occur as the revolution in modern biology progresses, there is every reason to make sensible preparations for dealing with relatively containable attacks using known agents.'[12] An example can be seen in the response to uncertain threat levels from anthrax and other biological weapons in the United States (US) following the 2001 attacks on the World Trade Center, and the postal anthrax attacks the following month. New regulations and increased funding for biodefence were responses to these new and unevaluated risks.

15. What role should public opinion play in the development of policy around emerging biotechnologies?

A conflict can arise in public health medicine between individual rights and the common good, making public participation in decision making important. Genetic screening, for example, may have beneficial effects for society but could lead to discrimination against particular groups. Public participation allows inclusive debate of the issues and potential responses. Public involvement is also more important where uncertainty around the uses and effects of such technologies may lead to public concern and require the sharing of information to lead to an informed public debate.

The BMA has previously noted in *Medical ethics today* that public involvement requires more than just listening to representatives of "target" populations. At its best it is an ongoing dialogue and involves providing population groups with information about individual policies, the reasons for implementing them, and the desired outcomes. Public health practitioners often involve the public in decisions. Doing so can make initiatives more successful, particularly among hard to reach populations.

An example of effective public involvement is the way the HFEA consulted and engaged the public in debate around the use of human admixed embryos during the 2007/08 review of the Human Fertilisation and Embryology Act 1990. The HFEA was seen as an impartial and effective communicator undertaking a robust consultation process. One method used was the deliberative dialogue process, where small diverse groups of the public exchanged ideas and discussed the issues around hybrid and chimera embryos. The results informed policy recommendations and led to the granting of licences to researchers under strict guidelines.

Methods of public involvement can include public consultations, representative panels, citizens' juries, focus groups, interviews and questionnaires (for details on the uses of these see *Medical ethics today*). It must also be acknowledged that although public involvement in decision making should be encouraged, it does not necessarily guarantee an ethically justifiable outcome.

I hope you find this information helpful, and I look forward to hearing the outcome of your consultation.

Professor Vivienne Nathanson
Director of Professional Activities

References

[1] British Medical Association (2007) *The use of drugs as weapons*. London: British Medical Association.
[2] British Medical Association (2005) *Population and genetic screening*. London: British Medical Association.
[3] British Medical Association (1999) *Biotechnology, weapons and humanity I*. London: British Medical Association.
[4] British Medical Association (2004) *Biotechnology, weapons and humanity II*. London: British Medical Association.
[5] British Medical Association (1998) *Human genetics: choice and responsibility*. London: British Medical Association.
[6] British Medical Association (1987) *Medical implications of biological and chemical warfare.* London: British Medical Association.
[7] British Medical Association (2004, updated 2009) *Medical ethics today*. London: British Medical Association.
[8] British Medical Association (1990) *Living with risk.* London: British Medical Association.
[9] British Medical Association (2004) *Genetically modified foods and health: a second interim statement.* London: British Medical Association.
[10] British Medical Association (2007) *Boosting your brainpower. Ethical aspects of cognitive ehancements*. London: British Medical Association.
[11] British Medical Association (2004) *Biotechnology, weapons and humanity II*. London: British Medical Association.
[12] British Medical Association (2004) *Biotechnology, weapons and humanity II*. London: British Medical Association.