

NUFFIELD COUNCIL ON BIOETHICS

Commentary on the proposal for a Declaration on Universal Norms on Bioethics by the International Bioethics Committee of UNESCO

The Nuffield Council on Bioethics¹ is grateful to the International Bioethics Committee (IBC) of UNESCO for the invitation to contribute to the deliberations towards a proposal for a Declaration on Universal Norms on Bioethics.

Due to the tight timetable of the IBC's consultation, the comments from the Nuffield Council are, at this stage, brief. They relate to the questions posed under I and II of page two of the *Outline Document*², circulated in preparation for the meeting.

Aims and scope of a Declaration on Universal Norms on Bioethics

The Nuffield Council has not formally considered a possible Declaration on Universal Norms on Bioethics (henceforth: *the Declaration*). Accordingly, the Council is not in a position to make a recommendation about the scope of the Declaration, or whether it should be extended to include animals, other living organisms, the environment and, for example, the use of GMOs.

However, we offer the following observations. To some degree, decisions about the scope of the Declaration would appear to depend on its intended function. II.5 of the Outline Document considers the possibility of providing guidance on specific subject areas by means of the Declaration. If such a function is indeed envisaged by the IBC, it might be appropriate to focus the Declaration on responsibilities of humans towards other humans only. The reason for this would be entirely pragmatic in nature. The Nuffield Council has recently considered issues arising from the use of genetically modified crops and is currently examining the ethics of research involving animals. As is well known, views differ considerably on these topics, both within the UK and internationally. If the IBC intends to cover these areas in its Declaration, and furthermore to provide guidance on them, the challenge to achieve consensus should not be underestimated.

¹ More detailed information about the Nuffield Council is at Annex B.

² *Outline for the preparation of the written contribution of organisations and institutions on the possible scope and structure of a declaration on universal norms on bioethics*, see http://portal.unesco.org/shs/en/file_download.php/f0a34803b0302b1f8d3928e44014f4500utline_en.pdf

It might be easier to achieve an extension of the scope of the Declaration beyond responsibilities of humans towards other humans, if the Declaration were confined to stating only “fundamental principles of broad application” (II.3).

Structure and Content of a Declaration on Universal Norms on Bioethics

As already stated, the Nuffield Council has not come to a formal opinion on the structure and content of the Declaration. However, we trust that some general observations as well as examples of important legal and ethical principles and concepts referred to in previous work of the Council might be of use to the IBC in its deliberations.

Specific comments regarding sections II.1, II.3., II.5 of the Outline Document

A preamble might be a useful means of clarifying the relation of the Declaration to other relevant documents such as UNESCO’s ***Universal Declaration on the Human Genome and Human Rights*** and its ***International Declaration on Human Genetic Data***; the Council of Europe’s ***Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine***; the World Medical Association’s (WMA) ***Declaration of Helsinki***; and the recent ***Charter of Fundamental Rights of the European Union***.

Furthermore, a preamble might be a useful means of explaining the function of the Declaration. The importance of clarity is illustrated by recent controversies concerning the ***Declaration of Helsinki*** (DoH).

As is widely recognised, views differ as to whether the DoH should be understood in the spirit of a Declaration, formulating a set of aspirational ideals, or whether it is more appropriately seen as a device which is virtually regulatory in nature, suitable for direct application to the conduct of research involving human participants. In practice, the DoH is often used in the latter way. It has, therefore, very real implications for the policy and practice of healthcare related research. However, due to the ambiguity of its status, a number of problems have arisen in interpreting the DoH’s provisions. The Nuffield Council addressed some of these in its 2002 Report ***The ethics of research related to healthcare in developing countries***.³

³ www.nuffieldbioethics.org/developingcountries

The relevance of the discussion in this Report has been underlined at a recent international Workshop on the same topic. The Workshop was co-hosted by the Nuffield Council and the South African Medical Research Council, in Cape Town from 12-14 February 2004.

One controversial area concerns the provision of treatment at the conclusion of a study. The DoH addresses this topic in Paragraph 30.⁴ Due to continuing disagreement about the meaning of this paragraph, the WMA established a Workgroup to provide guidance on how to clarify it. The Workgroup reported to the WMA General Assembly in 2003 with a proposal for a revision of Paragraph 30. However, the WMA was not able to agree on the proposal and established a second Workgroup, to report back in May 2004. The draft report of this Workgroup, published in January 2004,⁵ listed three options to resolve the disagreements:

- not to revise Paragraph 30, but to issue instead a separate statement or report on equitable access to healthcare
- to add a note of clarification setting out 'the intention of Paragraph 30', as attempted at the previous meeting;
- to add a preamble explaining that the Declaration is primarily a set of ethical principles, rather than a regulatory or legal device.

The draft report suggested that the preamble might read as follows:

'As a statement of principles, the Declaration of Helsinki is intended to establish high ethical standards that guide physicians and other participants in medical research involving human subjects. These ethical principles provide the basis of moral reflection on the means and goals of research involving human subjects, distinct from national legal and regulatory requirements. Interpreting the provisions of the Declaration regarding the design, conduct or completion of the research requires careful balancing of all of the Declaration's ethical principles. Differences in interpretation should be resolved by physicians and other participants involved in the research who are most familiar with all relevant factors, including the needs of research participants and of the host population.' WG/DoH/Jan2004, p. 3-4.

There may be merit in considering whether a similar preamble preceding the main provisions of IBC's Declaration might be a useful means of avoiding problems due to ambiguities. This section could clearly state what function the Declaration is intended to have. A clarification of its purpose would be particularly relevant with regard to Section II.5 of IBC's Outline Document, which considers the option of providing guidance on specific subject areas through the Declaration. If IBC indeed intends to pursue this option, it seems advisable to state so clearly. If not, it would seem similarly advisable to declare this.

⁴ 'At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study'

⁵ WG/DoH/Jan2004, Workgroup report on the revision of Paragraph 30 of the Declaration of Helsinki, available at: http://www.wma.net/e/ethicsunit/pdf/wg_doh_jan2004.pdf

The suggestion of providing guidance on specific subject areas by means of the Declaration raises one further issue which the Nuffield Council would like to bring to IBC's attention. We have noted above that achieving agreement on detailed provisions in relation to animal experimentation and the use of GM crops is unlikely to be straightforward. Similarly, reaching agreement will pose challenges in relation to issues raised by embryo and stem cell research. These topics are listed under II.5 of the Outline Document as possible areas which could be covered by guidance of the Declaration. Reaching agreement on these issues will pose significant challenges. As the IBC may be aware, the Nuffield Council argued in its 2000 Discussion Paper ***Stem cell therapy: the ethical issues***⁶, among other things, that:

'The proposed creation of embryos using SCNT (Somatic Cell Nuclear Transfer) for research into the derivation of stem cells offers such significant potential medical benefits that research for such purposes should be licensed' (paragraph 36).

Clearly, there is no agreement either within the EU, or globally, on the acceptability of such research, as was most recently apparent in discussions concerning a UN resolution on cloning. With regard to the possibility of including specific guidance in the Declaration on areas such as 'therapeutic' cloning, it would therefore appear unlikely, in the near future, to achieve the necessary consensus. Furthermore, the Nuffield Council notes that when IBC received the mandate to develop the Declaration at UNESCO's 32nd session in October 2003, the General Conference considered that universal standards should be set "in the spirit of cultural pluralism inherent in bioethics"⁷. The Nuffield Council endorses the recommendation to strive for universal standards which reflect sensitivity to cultural differences. With regard to issues raised by cloning and stem cell therapy, we interpret the General Conference's provision as stating that it would be inappropriate to ignore the diversity of views on such research. For example, the inclusion of principles or guidance which would limit research that some States perceive as valuable, responsible, and justifiable would not be acceptable in the Declaration. The Nuffield Council would therefore not be able to support a Declaration which provided restrictive guidance in this area.

Specific comments regarding section II.3 of the Outline Document

The question of which fundamental principles should be affirmed in the Declaration clearly depends on its aims and scope. Since such decisions are yet to be made, and since the Nuffield Council has so far not yet formally come to an opinion on the matter, we therefore cannot recommend specific

⁶ http://www.nuffieldbioethics.org/publications/pp_0000000007.asp

⁷ (32 C/Res. 24).

principles. However, the IBC may find the following notes useful in its deliberations.

Depending on the topic examined, Reports of the Nuffield Council have placed different emphasis on a range of ethical concepts and principles, as well as legal norms and rights. The list below gives some detail of relevant reference points, as referred to in the respective publications. Depending on the final scope of the Declaration, the IBC may wish to consider some of these in more detail.

- **Respect for persons, human dignity, free will and individual responsibility**

The Nuffield Council has discussed the concepts of 'personhood' and 'human dignity' exclusively in relation to born human beings.

- Mental disorders and genetics: the ethical context (1998)
- The ethics of research related to healthcare in developing countries (2002)
- Genetics and human behaviour the ethical context (2002)

- **The importance of genuine consent**

Consent is a cornerstone of ethical conduct in biomedical research involving human participants. The commonly used concept 'informed consent' can be misleading as consent can be given to a course of action only as described in a specific way and this description can never be exhaustive. 'Fully informed consent' is therefore an unattainable ideal. Consent should therefore be genuine. This requires primarily care in detecting and eliminating lack of consent.

- Genetic screening: ethical issues (1993)
- Human tissue: ethical and legal issues (1995)
- Animal-to-human transplants: the ethics of xenotransplantation (1996)
- Mental disorders and genetics: the ethical context (1998)
- Stem cell therapy: the ethical issues (2000)
- The ethics of research related to healthcare in developing countries (2002)
- Pharmacogenetics: ethical issues (2003)

- **Respect for autonomy, individual choice and freedom of conscience**

When considering the proper role of political authority in enforcing particular bioethical approaches, it is crucial to ensure that, as far as possible, individuals can exercise freedom of conscience in decisions relating to the use of new technologies.

- Genetic screening: ethical issues (1993)
- Animal-to-human transplants the ethics of xenotransplantation (1996)
- Genetically modified crops: the ethical and social issues (1999)
- Pharmacogenetics: ethical issues (2003)

- The use of genetically modified crops in developing countries (2003)
- **The right of the consumers and patients to adequate information about risks and benefits of new technologies**
 In order for people to make informed judgements and decisions about the use of new technologies it is important that factual and balanced information be provided by independent and trusted bodies
 - Genetically modified crops: the ethical and social issues (1999)
 - Genetics and human behaviour: the ethical context (2002)
 - Pharmacogenetics: ethical issues (2003)
 - The use of genetically modified crops in developing countries (2003)
- **The importance of ensuring non-discrimination**
 Medical research and especially genetic research entails the possibility that groups of people are discriminated unjustifiably on the basis of their genotype. Appropriate safeguards need to be put in place to prevent and counteract discrimination.
 - Genetic screening: ethical issues (1993)
 - Mental disorders and genetics: the ethical context (1998)
 - Genetics and human behaviour: the ethical context (2002)
 - Pharmacogenetics: ethical issues (2003)
- **The importance of ensuring confidentiality and privacy**
 Electronic means of storing and accessing personal biological and medical data have become increasingly common, especially with regard to genetic research. A careful balance needs to be struck to ensure that the conduct of important research is protected and that personal data of individuals participating in research is not used in inappropriate ways.
 - Genetic screening: ethical issues (1993)
 - Genetics and human behaviour: the ethical context (2002)
 - Pharmacogenetics: ethical issues (2003)
- **The duty to safeguard human health**
 In conducting biomedical research it is important to ensure that risks to the health of those participating as well as to the wider community are considered carefully. Failure to do so would show lack of respect for research participants, and may contribute to an unhelpful and negative perception of biomedical research.
 - Animal-to-human transplants: the ethics of xenotransplantation (1996)
 - Genetically modified crops: the ethical and social issues (1999)
 - The use of genetically modified crops in developing countries (2003)
- **The duty to safeguard animal health and welfare**
 In advancing the biomedical sciences, the species-specific capacities of animals involved in research need to be considered carefully, in

order to reduce negative welfare implications as far as possible. This can mean that certain animals should not be used for specific kinds of research.

- Animal-to-human transplants: the ethics of xenotransplantation (1996)

▪ **The importance of protecting the environment**

The consequences of using new technologies that can influence the environment need to be considered carefully. With regard to the consequences of agriculture and new technologies such as genetically modified crops, the Council is not persuaded that arguments based on 'naturalness' are useful in decision making. Rather, the focus should be on the acceptability of the consequences of new technologies on biodiversity.

- Genetically modified crops: the ethical and social issues (1999)
- The use of genetically modified crops in developing countries (2003)

▪ **The importance of furthering human welfare and the duty to alleviate suffering**

Technological advances in the biomedical sciences can contribute significantly to the improvement of human welfare in developed countries as well as in developing countries. It is important to explore the potential of new technologies in a responsible way.

- Genetically modified crops: the ethical and social issues (1999)
- Stem cell therapy: the ethical issues (2000)
- The ethics of research related to healthcare in developing countries (2002)
- The ethics of patenting DNA (2002)
- The use of genetically modified crops in developing countries (2003)

▪ **The duty to be sensitive to cultural differences, and the duty to avoid exploitation, especially of the vulnerable**

When applying principles or norms that are widely accepted in western traditions of bioethics to research taking place in other contexts, it is important to take into account the respective social, cultural and economic context.

- The ethics of research related to healthcare in developing countries (2002)

▪ **The importance of achieving a balance between the private and the public interest**

Research undertaken by the private sector has contributed significantly to furthering human welfare. Devices need to be in place to stimulate further research. However, it is important that the effect of such policies on the public interest are monitored. Some provisions, such as overly broad patents may be to the detriment of the public interest and inhibit research activity.

Specific attention is required when considering the effects of respective policies on developing countries.

- The ethics of research related to healthcare in developing countries (2002)
- Genetically modified crops: the ethical and social issues (1999)
- The ethics of patenting DNA (2002)
- Pharmacogenetics: ethical issues (2003)
- The use of genetically modified crops in developing countries (2003)

▪ **The importance of assessing carefully costs and benefits of using new technologies**

There may be certain courses of action that should be ruled out whatever their potential benefits. Such decisions require careful justification. Important questions to consider are: does the potential good outweigh the possible harm? What are the costs of not using a new technology?

- Genetic screening: ethical issues (1993)
- Animal-to-human transplants: the ethics of xenotransplantation (1996)
- The ethics of research related to healthcare in developing countries (2002)
- Genetically modified crops: the ethical and social issues (1999)
- Genetics and human behaviour the ethical context (2002)
- The use of genetically modified crops in developing countries (2003)
- Pharmacogenetics: ethical issues (2003)

▪ **The importance of achieving justice and equity, both locally and globally**

The dramatic differences in welfare of people living in developed and those living in developing countries are unacceptable. There are also significant global differences in the development of scientific and technological expertise. It is vital that the gap between countries at different stages of development is bridged. Some policies of European countries, for example with regard to agriculture, offer advantages to European consumers, but have a harmful effect on people in developing countries. Such policies need to be amended accordingly.

- Genetically modified crops: the ethical and social issues (1999)
- The use of genetically modified crops in developing countries (2003)
- The ethics of research related to healthcare in developing countries (2002)
- Genetics and human behaviour the ethical context (2002)
- Pharmacogenetics: ethical issues (2003)

Brief information about the Nuffield Council on Bioethics

The Nuffield Council on Bioethics was established by the Trustees of the Nuffield Foundation in 1991 to identify, examine and report on ethical questions raised by recent advances in biological and medical research. Since 1994, it has been funded jointly by the Nuffield Foundation, the Medical Research Council and the Wellcome Trust. The Council seeks to play a role in contributing to policy-making and stimulating debate in bioethics. It has published eight major reports on ethical issues associated with: genetic screening; ownership of tissue; xenotransplantation; genetics and mental disorders; genetically modified crops; research related to healthcare in developing countries; genetics and human behaviour and pharmacogenetics. The Council has also published four discussion papers dealing with ethical issues raised respectively by clinical research in developing countries, by research on human stem cells, patenting DNA and the use of GM crops in developing countries.

The terms of reference are as follows:

1. to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;
2. to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;
3. in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

Contact Address:

Nuffield Council on Bioethics
28 Bedford Square
London WC1B 3JS
Tel: + +44(0)20 7681 9619
Fax: + +44 (0)20 7637 1712
Web: www.nuffieldbioethics.org

Contact persons:

Mr Harald Schmidt, Assistant Director: hschmidt@nuffieldfoundation.org
Ms Nicola Perrin, Public Liaison Manager: nperrin@nuffieldfoundation.org