UNESCO's Universal Declaration on Bioethics and Human Rights

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Abstract

This essay describes the standard-setting activities of UNESCO in the area of bioethics, in particular the *Universal Declaration on Bioethics and Human Rights*. This Declaration has been adopted unanimously by the 191 member states in October 2005. The essay explains the reasons why member states asked for the preparation of this Declaration, its process of development and drafting by the International Bioethics Committee, and its contents. It further discusses the critical responses to the Declaration as well as its possible impact.

Keywords

Bioethics; declarations; United Nations

Introduction

On 19 October 2005 the 33rd General Conference of UNESCO, meeting in Paris, unanimously adopted the Universal Declaration on Bioethics and Human Rights [1]. This article explains the background, describes how the Declaration was developed, lists a number of its innovative provisions and examines the critical responses together with its possible impact.

When the United Nations Educational, Scientific and Cultural Organization (UNESCO) was established 60 years ago, its Constitution declared that peace must be founded upon the intellectual and moral solidarity of humanity. Julian Huxley, the first Director-General, pointed out that, in order to make science contribute to peace, security and human welfare, it was necessary to relate the applications of science to a scale of values. Guiding the development of science for the benefit of humanity therefore implied "the quest for a restatement of morality ... in harmony with modern knowledge" [2].

Since its foundation, UNESCO has been concerned with moral issues in relation to science. From the 1970s onwards, the emergence of the life sciences, in particular, has led to the international examination of bioethical questions. This global focus on bioethics was institutionalized in 1993 with the establishment of the International Bioethics Committee (IBC) with a work program and budget for international activities. The program was expanded in 1998 with the foundation by UNESCO of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), which is addressing other areas of applied ethics such as environmental ethics, science ethics and technology ethics. Since 2002 UNESCO has been coordinating the activities of international bodies in the area of bioethics through the Inter-Agency Committee on Bioethics of the United Nations (with, among others, FAO, OECD and WHO). In the same year, the 191 Member States decided that ethics should be one of the five priorities of the Organization.

Standard-setting

One major objective of the work of UNESCO in ethics has been the development of international normative standards. This is particularly important since many Member States have only a limited infrastructure in bioethics. They lack expertise, educational programs, bioethics committees, legal frameworks and public debate. Technological progress, new knowledge and its applications, new diagnostics, preventive and therapeutic interventions, have significantly changed medicine and the life sciences as well as the context of health care, giving rise to bioethical dilemmas both in highly developed and less developed countries. Further, Bioethics is no longer the exclusive concern of scientists, medical professionals, or policy-makers. It concerns all people. Disease, disability, death and suffering are human experiences that sooner or later affect everybody. This is all the more true from an international perspective. Because of globalization, not only scientific and technological advances spread around the globe, but also bioethical dilemmas. As the example of cloning demonstrates, when a new technology has been developed in one country, it can be applied elsewhere, even if some countries want to ban its use. On the other hand, bioethical issues may arise because of inequality and injustice. If an effective medication for diseases such as HIV/AIDS, malaria and tuberculosis is available in some countries, it is morally problematic when patients die in countries because of a lack of resources. It is not acceptable that research institutes and pharmaceutical companies carry out clinical trials in developing countries without applying the same standards of informed consent and risk assessment as in developed countries. The global character of contemporary science and technology and the increasing number of research teams coming from different countries suggest the need for a global approach to bioethics. This is precisely what UNESCO aims to promote.

International bioethics

In the past UNESCO has previously adopted two declarations in the field of bioethics: the *Universal Declaration on the Human Genome and Human Rights* (1997) and the *International Declaration on Human Genetic Data* (2003). The scope of standard-setting was expanded significantly with the mandate given by the Member States to develop a universal declaration on bioethics [3]. The previous declarations had focussed on the specialized area of genomics and genetics. When the new mandate was given, all topics relevant to bioethics were placed on the table for negotiation. In October 2001, the General Conference, supported by the Round Table of Ministers of Science, invited the Director-General of UNESCO to examine the possibility of developing a universal instrument on bioethics. The feasibility study drafted by the International Bioethics Committee concluded that it was possible to find common ground in divergent bioethical positions by focusing on basic principles [4]. Some of these principles had already been identified in previous declarations. The study also stressed the necessity to develop a universal instrument because scientific practices are now developing rapidly and extending beyond national borders. Developed and developing countries should therefore achieve broad consistency in the principes informing their regulations and policies.

In October 2003, the General Conference provided a mandate to submit a draft declaration in two years. In the meeting, the French President (Mr J Chirac) made a vigorous plea for a universal normative framework, preferably a Convention, to guide the progress of the life sciences and to protect the integrity and dignity of human beings. Taking into account the short time frame, the variety of ethical cultures and traditions, and the controversial nature of many bioethical issues, the subsequent process of drafting, entrusted to the IBC, was based on extensive consultations with many organizations (e.g. FAO, WHO, WIPO, Council of Europe, National Bioethics Committees and international bioethics societies). During the elaboration of the text, drafts, at various stages of the elaboration process, were published on the website of UNESCO. The work of the IBC drafting group was therefore conducted in as public a way as possible in order to facilitate consensus formation and early identification of any dissenting views.

Dealing with bioethics in an intergovernmental organization such as UNESCO implies a linkage between science and politics. Any normative instrument needs to reflect the scientific and ethical state of the art. But in the end any draft is submitted for approval to the Member States which then decide if they want to adopt it. The draft text developed by independent scientific experts of the IBC was necessarily subjected to political negotiations amongst the governmental experts who represented the governments of Member States. The result is that the cogency of the final text, in some respects, may be diminished in order to create maximum adherence by all of the governments involved. In order to facilitate the opportunities for compromise, the work of the independent IBC was connected at an early stage with that of governmental experts. Several amendments to the IBC text were made by the governmental experts. The Declaration, as adopted, represents the IBC draft as so amended.

The contents of the new Declaration

One of the contentious issues in the elaboration was the scope of bioethics. At least three views were advanced. These were that bioethics had to do with (1) medicine and health care, (2) the social context, such as access to health, and (3) the environment. In different parts of the world, different conceptions, definitions and histories of bioethics were evident.

The scope of the adopted text of the Declaration is an obvious and valid compromise between these views. It addresses "ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions" (Art 1a).

The aims of the Declaration are multiple. However, the most important aim is to provide "a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics" (Art 2i). One characteristic of present-day bioethics is that it is not merely an academic discipline; it is also an area of public debate and policy-making. This is why the Declaration primarily addresses States. But at the same time, since the bioethical principles identified are founded on human rights and fundamental freedoms, every individual is involved in bioethics. The Declaration, therefore, also aims "to guide the actions of individuals, groups, communities, institutions and corporations, public and private" (Art 2).

The heart of the Declaration is to be found in the 15 principles that are listed (see Annex). The principles express the different obligations and responsibilities of the moral subject ('moral agent') in relation to different categories of moral objects ('moral patients'). The principles are arranged according to a gradual widening of the range of moral objects: the individual human being itself (human dignity; benefit and harm; autonomy), other human beings (consent; privacy; equality), human communities (respect for cultural diversity), humankind as a whole (solidarity; social responsibility; sharing of benefits) and all living beings and their environment (protecting future generations and protection of the environment, the biosphere and biodiversity).

Some of the principles are already widely accepted (e.g. autonomy; consent). Others have been endorsed in previous Declarations (e.g. sharing of benefits). What is innovative in the set of principles in the new Declaration is the balance struck between individualist and communitarian moral perspectives. The Declaration recognizes the principle of autonomy (Art.5) as well as the principle of solidarity (Art.13). It emphasizes the principle of social responsibility and health (Art. 14) which aims at re-orienting bioethical decision-making towards issues urgent to many countries (such as access to quality health care and essential medicines especially for women and children, adequate nutrition and water, reduction of poverty and illiteracy, improvement of living conditions and the environment). Finally, the Declaration anchors the bioethical principles firmly in the rules governing human dignity, human rights and fundamental freedoms.

The section on the application of the principles (Arts 18 to 21) is also innovative because it expresses the spirit in which the principles ought to be applied. It calls for professionalism, honesty, integrity and transparency in the decision making process;

the setting up of ethics committees; appropriate assessment and management of risk; and ethical transnational practices that help in avoiding exploitation of countries that do not have an ethical infrastructure.

Critical responses

Although reflections on the Declaration are just beginning to appear, critical responses have focused on four issues: (a) the mandate of UNESCO, (b) the nature of the text, (c) the connection of bioethics and human rights, and (d) the primacy of individual values.

Concerns have been raised that with the Declaration UNESCO is "meddling in the professional domain of another United Nations (UN) agency, WHO" [5, 6]. However, UNESCO is an organization of member states, like WHO. It is up to them to decide which organization deals with bioethics. Moreover, UNESCO has had a strong involvement in bioethics for more than a decade. It has produced not only 3 Declarations in this area but a long series of detailed reports of the IBC on various salient bioethical issues. UNESCO is the only UN agency with a mandate in science. Setting up a strong program in bioethics recognized the fact that many bioethical problems are connected with science and technology. The fact that most bioethical problems nowadays are connected with developments in science and technology has probably been the major motive for governments to initiate and reinforce the ethics program of UNESCO. Furthermore, UNESCO has initiated the establishment of the UN Interagency Committee on Bioethics in 2003 which provides a platform for exchange of information and coordination of activities with other UN agencies working in different domains of ethics, such as FAO, WHO and WIPO).

The nature of the Declaration has sometimes been misunderstood. It has been criticized as having eliminated "all new obligations of states" [6], as a document characterized by minimalism and vagueness [7], being produced by experts that are not really experts [5] . But what is a weakness for some is strength for others. Indeed in international law it is clear that a UN Declaration does not have binding force but nevertheless it "commands a certain respect" [8]. Because the text is ultimately adopted by governments, it is necessarily the result of compromise. Underlying this second criticism seems to be a difference of opinion about what bioethics essentially is. Is it an academic discipline and "not the playground for government appointed politician-experts"? [5]. The history of bioethics in many countries shows that it is a public movement (emphasizing patient rights and public debate) and policy issue (resulting in health legislation and international treaties) as much as an academic discipline. The role of bioethics in many parts of the world is no longer primarily focused on studies interpreting certain dimensions of the world but rather it focusses on change of at least some dimensions (and thus bioethics nowadays is involved in policy-making).

The third source of criticisms has addressed the relationship between bioethics and human rights. The claim that human rights do not feature prominently in bioethics [5] is not supported by facts. International documents such as the European Convention on Human Rights and Biomedicine, and the WMA Declaration of Helsinki refer to human rights (and human dignity). The UNESCO Declaration continues this appeal to human rights in establishing global bioethics principles. The connection with human rights was already made in the 1997 *Universal Declaration on the Human Genome and Human Rights*. Some scholars have recently pointed out that the Declaration's grounding of bioethics in universal human rights will bring international bioethics into a new phase of involvement with regulation and implementation, being accepted as part of international law. Eventually, it may be expected that the new Declaration will become the starting point for an international bioethics convention [9, 10].

The fourth criticism questions the relationship between universal and culture-related values [5, 7]. It is argued that the Declaration, for example in Article 3, gives primacy to individual interests. Examining the listed principles, it is however remarkable that agreement was reached on a much broader range of principles, beyond the individually orientated ones. It is true that no hierarchy is given among the several principles. Nonetheless, Article 3 is remarkable since is has exactly similar wording as other documents (such as the Declaration of Helsinki). The key word in the Article, in fact, is "sole"; if society is seriously threatened, for example, by a pandemic, individual interests can be restricted, as expressed in Article 27. It remains to be seen whether the right balance has been struck between universal human values and cultural differences [11] and what will be the usefulness of the Declaration in the diverse practices of bioethics. At the same time, the Declaration contains an expression of a major characteristic of bioethics: Bioethical problems commonly arise because conflicts exist between several competing ethical principles. Sometimes it is not obvious which principle will prevail. Accordingly, a careful balancing of principles is usually required. The new Declaration states principles that may occasionally seem inconsistent. However, ethical decision-making in practice frequently requires rational argumentation and the weighing of the competing principles at stake. In order to advance decision-making, the principles are to be understood as complementary and interrelated (Art.26).

Implications and impact

It is significant that all 191 Member States of UNESCO were able to agree upon the relevant bioethical principles. Although the Declaration is a non-binding legal instrument, it is the first international document in bioethics adopted by all governments. Other very influential documents have been adopted by non-governmental organizations (e.g. the Declaration of Helsinki). However, generally, these do not create the same commitment on the part of governments.

It is important to note that the UNESCO Declaration has already been cited as relevant international text in the recent judgment of the European Court of Human Rights in the Case of Evans v the United Kingdom [12]. Furthermore, the new Declaration is the beginning rather than the end of a process of internationalization of bioethics. Special attention therefore needs to be given to the application of the principles and the dissemination and the promotion of the Declaration. Member States that have not already done so are incouraged in the Declaration to establish bioethics committees; to promote informed pluralistic public debate; to foster bioethics education and training; and to take appropriate legal measures to facilitate transnational research.

The ethics program of UNESCO has initiated three programs to promote the application of the principles of the Declaration in the Member States. First, the Global Ethics Observatory (GEO) has been set up to provide data concerning ethics experts and institutions, committees, societies in all UNESCO Member States, as well as detailed information concerning existing ethics teaching programs [13]. At the moment, groups of experts are developing materials and data for a comparative international database of legislation and guidelines in the domain of bioethics. Second, the Ethics Education Program is mapping ethics teaching programs and creating networks of experts in this area in order to exchange detailed information on existing teaching programs and to promote the development of new ones . A committee of experts is drafting a proposal for a core curriculum in bioethics, based on the Declaration. At the same time UNESCO is offering a training course for ethics teachers (with the first such course in Bucharest, Romania in November 2006). Third, the Assisting Bioethics Committees project is providing practical information about the establishment of ethics committees and the work methods and procedures of committees [14]. Task forces of experts have been set up that are offering technical assistance to countries wishing to establish such committees.

International organizations such as UNESCO will continue to assist countries to develop an ethical infrastructure so that human beings everywhere can benefit from the advances of science and technology within a framework of respect for human rights fundamental freedoms and cultural diversity..

For centuries bioethical concerns have been mainly addressed in two separate fields of discourse. Relevant basic principles have been promulated in the health sciences and also in legal rules expressing basic civil rights. The great merit of the new UNESCO *Universal Declaration on Bioethics and Human Rights* is that it brings these two streams together; does so at a global and universal level accepted by 191 nation states; and places the combined statement in a wider setting concerned with the protection of future generations of human beings and of the environment and biosphere of all living things. It may be hoped that those concerned with bioethical questions everywhere will rise to its challenge.

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ANNEX

UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS – PRINCIPLES

Article 3 – Human Dignity and Human Rights

Human dignity, human rights and fundamental freedoms are to be fully respected.

The interests and welfare of the individual should have priority over the sole interest of science or society.

Article 4 – Benefit and Harm

In applying and advancing scientific knowledge, medical practice and associated techologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 – Autonomy and Individual Responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 6 - Consent

a) Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

b) Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include the modalities for withdrawal of consent. The consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

c) In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Article 8 – Respect for Human Vulnerability and Personal Integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 9 – Privacy and Confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

Article 10 – Equality, Justice and Equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11 – Non-Discrimination and Non-Stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 12 – Respect for Cultural Diversity and Pluralism

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Article 13 – Solidarity and Cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

Article 14 – Social Responsibility and Health

a) The promotion of health and social development for their people is a central purpose of governments, that all sectors of society share.

b) Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:

- (i) access to quality health care and essential medicines, including especially for the health of women and children, because health is essential to life itself and must be considered as a social and human good;
- (ii) access to adequate nutrition and water;
- (iii) improvement of living conditions and the environment;
- (iv) elimination of the marginalization and the exclusion of persons on the basis of any grounds; and
- (v) reduction of poverty and illiteracy.

Article 15 – Sharing of Benefits

a) Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

(i) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;

(ii) access to quality health care;

(iii) provision of new diagnostic and therapeutic modalities or products stemming from research;

(iv) support for health services;

(v) access to scientific and technological knowledge;

(vi) capacity-building facilities for research purposes; and

(vii) other forms of benefit consistent with the principles set out in this Declaration.

b) Benefits should not constitute improper inducements to participate in research.

Article 16 - Protecting Future Generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17 – Protection of the Environment, the Biosphere and Biodiversity

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to the respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity