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The UNESCO Universal Declaration *on* Bioethics *and* Human Rights

Background, principles and application

Edited by Henk A. M. J. ten Have
and Michèle S. Jean

Ethics series

The UNESCO Universal Declaration on Bioethics and Human Rights

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CONTENTS

PREFACE

In October 2005, the General Conference of UNESCO adopted by acclamation the Universal Declaration on Bioethics and Human Rights. The Declaration 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, and states fundamental principles that are relevant from a global perspective. It is the first time in the history of bioethics that Member States committed themselves and the international community to respect and apply such fundamental principles.

Since its adoption, the Declaration has very quickly become a reference text. A growing number of scholarly and popular publications are discussing and examining the Declaration. Several books have been published in various languages analyzing the provisions of the Declaration. The text of the Declaration has been translated into approximately 30 national languages. The Declaration is also increasingly used as a resource and as teaching material in educational programmes for young scientists and health care professionals. UNESCO is currently developing a proposal for a bioethics course based on the principles set out in the Declaration. The Declaration has furthermore inspired Member States to establish national bioethics committees and to take legislative measures to give effect to the principles included in the Declaration.

The present book provides a new impetus to the promotion and dissemination of the Declaration and is part of the continuous effort of the Organization to provide information on the Declaration worldwide and to contribute to the understanding of its principles. Presenting an article by article commentary, each chapter highlights the discussion of the relevant article during the process of drafting and elaborating the Declaration so that the historical background of the adopted text is clarified. It also provides suggestions for the use and application of the relevant article in considerations and debates concerning salient bioethical issues and questions. In doing so,

each chapter promotes opportunities for informed pluralistic public debate, as requested in the Declaration itself.

The chapters have been written by authors who, with a few exceptions, have themselves been involved in the drafting and elaboration of the text of the Declaration, as members of the International Bioethics Committees, the Intergovernmental Bioethics Committee or as governmental representatives in expert meetings, the Executive Board and the General Conference. It is obvious that what they present is not the official view of UNESCO as regards the interpretation of the Declaration. But the authors' involvement in the development of the Declaration in its various stages assures well-informed and high-level contributions to the promotion of the Declaration.

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Chapter 1

INTRODUCTION

Henk A.M.J. ten Have and Michèle S. Jean

On 19 October 2005 the 33rd General Conference of UNESCO, meeting in Paris, unanimously adopted the Universal Declaration on Bioethics and Human Rights (UNESCO, 2005a). This chapter explains the historical background of the Declaration, describes in detail how the Declaration was developed, lists a number of its innovative provisions and examines the responses together with its possible impact. It also introduces the contributions to this volume.

UNESCO AND ETHICS

When the United Nations Educational, Scientific and Cultural Organization (UNESCO) was established 62 years ago, its Constitution declared that peace must be founded upon the intellectual and moral solidarity of humanity. Julian Huxley, the first Director-General of the Organization, 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' (Huxley, 1946: 41).

Since its foundation, UNESCO has been working in four areas: education, culture, science and communication. UNESCO currently has 193 Member States (one more than the UN General Assembly in New York). All Member States meet once every two years (nowadays in Paris) for three weeks to discuss all issues pertaining to the functioning of the Organization. In this General Conference they also determine the programme for the next two years, specifying the main activities, their objectives and budgets. The activities are implemented by the Director-General (who is elected every four years by the Member States). The Director-General selects and appoints international civil servants with competencies and expertise in the areas of the work of the Organization. They work either in the Headquarters in Paris

or in Field Offices in regions, sub-regions and countries. Together, all civil servants constitute the Secretariat of the Organization. They are recruited from all Member States. The Secretariat therefore is already a microcosm of cultures, traditions, languages and experiences. However, the civil servants must follow the instructions of the Director-General (and thus the decisions of the General Conference) and not those of individual Member States.

Being a specialized UN organization provides at least two characteristics for UNESCO and its work. First, the activities should be focused on accomplishing goals that are relevant for all Member States. Consequently its activities in promoting science and international co-operation should serve as a channel to address the basic problems and needs of the world population. Science therefore is not regarded as an end in itself but as a means towards the development of nations and the resolution of global problems such as poverty, environmental degradation and child mortality. Since 2000 the eight Millennium Development Goals are the overarching goals for the world community to be achieved by 2015.

Second, the activities of the Organization should take into account all perspectives that are relevant to all Member States. In order to facilitate this, six official languages are used in the Organization: Arabic, Chinese, English, French, Spanish and Russian, while English and French are the daily working languages. Respect for cultural diversity is one of the main concerns of UNESCO. It has put in place programmes to preserve and protect cultural accomplishments in, for example, architecture, arts, literature, philosophy and science. These programmes have been implemented in specific historical, religious and cultural settings. UNESCO, through its efforts to identify such accomplishments in all regions of the world, is showing that all civilizations and cultures have contributed to the present condition of humankind. However, in all this richness and diversity, one can also discover the expression of common values and shared interests. In fact, UNESCO is directed by its Constitution, adopted in November 1945, affirming that the purpose of the Organization is '…to contribute to peace and security by promoting collaboration among the nations through education, science and culture in order to further universal respect for justice, for the rule of law and for the human rights and fundamental freedoms…' (UNESCO, 1945, Article 1.1). The same principles are affirmed in the Charter of the United Nations, adopted a few months earlier that same year: fundamental human rights, the dignity and worth of the human person, and equal rights of men and women and of nations large and small (UN, 1945: Preamble). The tensions between respecting diversity and affirming universality are noticeable

in all areas of work but they are particularly sensible when values, rights and principles are concerned.

Since its foundation, UNESCO has been concerned with moral issues in relation to science. Within the United Nations system UNESCO is the only specialized agency with a mandate in the sciences. 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). This also urged the Secretariat to set up a special unit with a work programme and budget for international activities in bioethics. The programme was expanded in 1998 with the foundation by UNESCO of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), which addresses other areas of applied ethics such as environmental ethics, science ethics and technology ethics. Today, as many UN organizations and other international and regional intergovernmental bodies, such as the European Commission, the Council of Europe and the African Union, have activities in the field of bioethics, in 2002 UNESCO's Director-General took the initiative to establish the Inter-Agency Committee on Bioethics of the United Nations (with, among others, the Food and Agriculture Organization (FAO), the International Labour Organization (ILO), the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO)) for which UNESCO provides the permanent secretariat. In the same year, the Member States decided that ethics of science and technology, in particular bioethics, should be one of the five priorities of UNESCO (ten Have, 2006a).

STANDARD-SETTING

One major objective of the work of UNESCO in ethics has been the development of international normative standards. The United Nations, in fact, provide the only existing platform for all nations to explore and discuss the values and principles that they share, and to negotiate and agree on normative instruments. Other efforts to determine common standards have been undertaken at regional levels. The Council of Europe has done exemplary work in the area of bioethics with the drafting and adoption of the European Convention on Human Rights and Biomedicine, signed in Oviedo in 1997 and enforced in 1999 (Council of Europe, 1997). This Convention demonstrates the existence of an agreement at the regional level. For a global perspective, the UN organizations provide the only possible framework. UNESCO has stated

that in fulfilling its mission it will carry out for the international community five functions: 1) laboratory of ideas, 2) standard-setter, 3) clearing house, 4) capacity-builder, and 5) catalyst for international co-operation (UNESCO, 2007a). Standard-setting implies the search for universal agreements. While all countries are confronted with global challenges, a delicate balance needs to be produced between developing universal principles and norms based on shared values on the one hand, and promoting pluralism through recognition and enhancement of diversity on the other hand. Reaching such a balance is particularly important for bioethics since it is a relatively new area with many controversies. Bioethics is also a multidisciplinary field. It has emerged in academic settings and has developed into an established scientific discipline in medical, legal and science departments. It has become an area of policy and decision-making, with usually diverging political approaches. For many issues there is nowadays a need for regulation and legislation, for example regarding medical research, genetics and transplantation. But there are also very controversial issues such as abortion, euthanasia and stem cell research that require policies and guidelines. Bioethics is furthermore a domain of public debate and the subject of many discussions in newspapers and on the radio and television. The public is increasingly aware of its rights and of the difficult choices to be made concerning bioethics.

Because of these characteristics, standard-setting in bioethics requires the involvement of many different stakeholders: scientists, lawyers, policy-makers and citizens.

Within UNESCO, the process of standard-setting aims at the involvement of heterogeneous stakeholders, to make sure that the best conditions exist for the emergence of consensus during the process of developing normative instruments. UNESCO is following a multi-stage procedure for the elaboration, examination, adoption and follow-up of declarations that have been determined by the Member States. Independent experts (in the International Bioethics Committee as the permanent body) will start to make the first draft, whereupon intergovernmental meetings will enter into negotiations. In the development of the Universal Declaration on Bioethics and Human Rights, therefore, different bodies have been involved during the various phases of its development:

- The *International Bioethics Committee* (IBC). This body of experts, established by UNESCO in 1993 is the only ethics committee with a truly global scope (Jean, 2006). It is composed of 36 experts in different disciplines: genetics, medicine, law, philosophy, ethics, history, and social sciences. They are appointed by the Director-General of

UNESCO as independent experts who can provide him with the best possible advice. The IBC also takes into account the fact that experts come from different regions and have different backgrounds – professionally, culturally and morally. They do not represent their Member States and are not expected to follow any instructions from them. They only represent themselves and are members of the Committee because of their scientific expertise and qualifications. They report directly to the Director-General. The main mission of the Committee is to provide recommendations to the Director-General that reflect the best possible expertise in the scientific domain. The Committee meets at least once a year. It can also create subsidiary bodies like working groups that elaborate particular issues and make draft reports that are then adopted by the Committee. In the past, IBC has produced a long series of reports, covering controversial issues such as genetic screening and testing (IBC, 1994), the use of embryonic stem cells in therapeutic research (IBC, 2001) and pre-implantation genetic diagnosis and germ-line intervention (IBC, 2003a). The sessions of the Committee are usually open in order to provide the opportunity for various stakeholders from the scientific community, the policy-making arena and the general public to comment on the activities and products of the Committee.

- The *Intergovernmental Bioethics Committee* (IGBC). This Committee, not to be confused with IBC, was established by the Member States in 1998. It is composed of 36 Member States that are elected by the General Conference, taking into account cultural diversity and geographical representation. Members of this Committee are therefore States. Who is chosen to represent the States is the prerogative of the States who are members of this Committee. Sometimes they are professional bioethicists or lawyers, sometimes scientists or physicians; at other times officials from a ministry or an embassy. They meet at least once every two years to examine the advice and recommendations of the IBC. It informs the IBC of its opinions and submits these opinions along with proposals for follow-up on the IBC's work to the Director-General for transmission to Member States, the Executive Board and the General Conference.
- *Governmental experts meeting*. In the case of an important document, such as a draft declaration, it will be submitted for approval to the Member States. To do so, the Director-General will convene a meeting of representatives of all governments to discuss, review and revise

the draft text submitted by different committees. In this case, and following an official procedure of invitation and delegation, experts from potentially all Member States will gather to finalize the text in order to present it for adoption at the General Conference. These meetings are usually the main platforms to hold negotiations among Member States on the final text.

- *Executive Board*. This is one of the so-called governing bodies of UNESCO. Its 58 members are elected at the General Conference. The Executive Board meets twice a year. It prepares the work of the General Conference and sees that the decisions made are properly carried out. The functions and responsibilities of the Executive Board are derived primarily from the Constitution of UNESCO and from rules or directives laid down by the General Conference. If a mandate has been given to draft a declaration, the Director-General has regularly to report on the progress of the work (in this case the activities of the IBC).
- *General Conference*. This body consists of the representatives of the Member States of the Organization. It meets every two years, and is attended by Member States and Associate Members, together with observers from non-Member States, intergovernmental organizations and non-governmental organizations (NGOs). Each country has one vote, irrespective of its size or the extent of its contribution to the budget. The decision whether or not to develop a normative instrument will be taken by the General Conference. It then gives a mandate to the Director-General, who also has to submit the draft within a particular time frame. The General Conference will then adopt the declaration, usually by acclamation, which means that the draft text will only be submitted for adoption after the preceding negotiations have been successful.

PAST EXPERIENCES

The standard-setting activity of UNESCO in the area of ethics of science is important, since many Member States have only a limited infrastructure in bioethics. They lack expertise, educational programmes, bioethics committees, legal frameworks and public debate. Technological progress, new knowledge and its applications, new diagnostics and preventive and therapeutic interventions have significantly changed medicine and the life sciences, as well as the context of public health and 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, lawyers or policy-makers. It concerns all people. Disease, disability, death, suffering and issues related to the beginning and the end of life are part of the human experience. This is all the more true from an international perspective. Because of globalization, not only have 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 and AIDS, malaria and tuberculosis is available in some countries, it is morally problematic when patients die in other 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 at promoting. Since it provides a global platform to identify shared values and to assert universal principles, it can give guidance to Member States that up to now lack the ethical infrastructure, and particularly the legislation to deal with present-day bioethical challenges. Because UNESCO must take into account all relevant perspectives and pay attention to all value systems, the standards developed do not impose one particular moral view or one specific ethical approach on its members.

UNESCO's interest in bioethics dates back to the 1970s. In that same period of time, bioethical concerns emerged in many countries. In 1970, the word 'bioethics' was introduced by Potter, who used a broad definition of the concept (Potter, 1971). The same era witnessed revolutionary changes and innovations in medical diagnosis and treatment, but also in science and technology. Additionally, scandals, misuse and injustices came to light and alarmed the public and policy-makers, leading to the first establishment of bioethics centres, ethics committees, review boards and efforts to codify patients' rights and to regulate the medical and biomedical research community (Rothman, 1991). UNESCO started to organize symposia and conferences on bioethics in 1970, mainly related to the development of genetics, life sciences and reproductive technologies and in co-operation with UNESCO's Scientific Co-ordinating Committee for the Human

Genome Project (UNESCO, 1993). Member States have been particularly concerned about the relationship between scientific and technological progress and human rights (UNESCO, 1987). In June 1992, Federico Mayor, then Director-General of UNESCO, decided to set up an International Bioethics Committee, chaired by Noëlle Lenoir, a member of the Constitutional Council of the French Republic. The most important task of the Committee was to explore how an international instrument for the protection of the human genome could be drafted. The Committee met for the first time in September 1993. In the meantime, a Scientific and Technical Orientation Group was formed in December 1992, carrying out preparatory studies. The Group conducted extensive consultations, focusing on five themes: genome research, embryology, neurosciences, gene therapy, and genetic testing. For each theme various dimensions were studied: the current state of progress in research at the world level, the application of the results of this research, and the principal ethical concerns for the present and for the future. On the basis of these studies, the Group identified the reference points likely to secure the broadest agreement, proposing principles that were most likely to respond to the ethical concerns.

The IBC started its work with the consideration that in the history of humankind science has always influenced the evolution of civilizations throughout the world, and in that respect genetics would not be different. Like all scientific discoveries, the application of genetics will cause concerns, but it will be important to go beyond the focus on the dangers of deviation and infringements of human rights. The IBC also took into account cultural diversity ('ethical positions depend on the value systems specific to each society in accordance with its cultural traditions') but also universality ('the internationally recognized idea of *universality* on which human rights are founded is crucial to ethics') (UNESCO, 1993). At this stage, the Committee proposed a framework of ethical principles for a possible international instrument for the protection of the human genome.

In November 1997, the General Conference adopted by acclamation the Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997). It was endorsed a year later by the General Assembly of the United Nations. It therefore became the first normative instrument on bioethics adopted by UNESCO. One of the fundamental principles in the declaration is the principle of respect for human dignity.

As a sequel to the Universal Declaration, the International Declaration on Human Genetic Data was adopted by the General Conference of UNESCO in October 2003 (UNESCO, 2003b). It states the principles

related to the collection, processing, storage and use of human genetic data. It is important to note that both declarations incorporate follow-up mechanisms to promote dissemination, application of, and respect for, the principles and standards established (Yusuf, 2007).

The scope of standard-setting was expanded significantly with the mandate given by the Member States to develop a universal declaration on bioethics. The previous declarations had focused on the specialized area of genomics and genetics. When the new mandate was given, all topics relevant to bioethics were, in principle, placed on the table for negotiation.

PREPARATIONS

The Director-General decided to organize a Round Table of Ministers of Science on bioethics during the 31st session of the General Conference in October 2001. Ministers and Vice Ministers of Science of 52 Member States and representatives of the Ministries of Science of 49 others participated in the Round Table. The aim was to exchange views on bioethical issues at the international level. The participants discussed basic principles in bioethics. They agreed on the need to draft a 'universal instrument on bioethics' (UNESCO, 2002). In the final Communiqué, the participating and represented Ministers of Science underlined that the questions raised by today's bioethics are 'so international in scope that they transcend all boundaries' and that there is 'a close relationship between science and the future of humanity'. On this basis they invited the United Nations and the specialized agencies of the United Nations system to draw freely on the competence of UNESCO, 'a leading agency in bioethics at the international level', in order to 'avoid all duplication of efforts'. More importantly, they invited UNESCO to 'examine the possibility of developing … a universal instrument on bioethics…' (UNESCO, 2003a).

The General Conference, in session at the same time as the Round Table, decided to confirm UNESCO's leading position in bioethics by including ethics of science and technology among the five priorities of the Organization. The General Conference also adopted a resolution inviting the Director-General to submit 'the technical and legal studies undertaken regarding the possibility of elaborating universal norms on bioethics' (UNESCO, 2001). The Director-General requested the IBC to carry out this feasibility study.

The IBC decided to set up a working group. In the following two years the group produced a report that was discussed in IBC meetings in

Montreal (2002) and in Paris (2003), and finalized in June 2003 (IBC, 2003b). It argues that a universal instrument is feasible; it will 'serve the interests of the international community as a whole, and of disadvantaged people in particular' (IBC, 2003b: 12). It also recommends that the instrument should be a declaration; this will allow for the re-examination and eventually the revision of the instrument at regular intervals. The IBC report furthermore examines issues in bioethics that could be addressed in such an instrument, for example access to health care, assisted reproduction, genetic enhancement, end of life issues, and research involving human subjects. This overview of sometimes very controversial topics is not presented as a comprehensive list of specific issues to be covered by the universal instrument, but illustrates the range and nature of the problems encountered and the need to search for a common ground, focusing on the basic principles of bioethics.

Later in June 2003, the IGBC examined the IBC report. The members emphasized the need for broad consultations in order to involve the different stakeholders concerned; they agreed with the need to draw up a universal text on bioethics as well as with the IBC proposal that a possible instrument be non-binding and that it focus on the fundamental principles of bioethics (UNESCO, 2003c).

THE MANDATE

In October 2003, the 32nd session of the General Conference considered that it is opportune and desirable to set universal standards in the field of bioethics. It decided to invite the Director-General 'to continue preparatory work on a declaration on universal norms on bioethics … and to submit a draft declaration at its 33rd session' (UNESCO, 2003d). During the session, Jacques Chirac, President of France, made a vigorous plea for a universal normative framework, preferably a convention, to guide scientific progress and to protect human dignity. His view was that the international community has a need for scientific ethics and rules to protect the integrity and dignity of human beings because of new ethical questions and new threats and abuses. He argued that France felt that a convention would be the most successful means. Adopting a universal declaration to enshrine the fundamental principles would be one of the first steps towards this goal (Présidence de la République Française, 2003).

Immediately after receiving the mandate, the Director-General of UNESCO entrusted the IBC with the drafting of a preliminary text.

ELABORATING AND DRAFTING

Aware that the time frame included in the mandate was very short (in fact the General Conference requested a draft declaration within less then two years, i.e. before September 2005), the IBC, chaired by Michèle S. Jean, immediately set out to develop a timetable and methods of work that would allow for an extensive consultation process. In December 2003, the Bureau of the IBC met in Rome, Italy, and also had a joint meeting with the Bureau of the IGBC. Mechanisms for co-operation and linkage between the two Committees concerning the drafting of the future declaration were examined. Both Bureaus stressed the importance of consultations at every level throughout the drafting process.

The timetable for drawing up the declaration, established in consultation with the IBC and IGBC Bureaus, consisted of three key stages: (1) extensive consultations from the outset on the scope and structure of the declaration, in written form with Member States, in the form of hearings with intergovernmental and NGOs and national bioethics committees, and in the form of conferences with national experts; (2) the actual drafting of the declaration by IBC, supported by consultations; and (3) the finalization of the text at meetings of governmental experts.

1. Consultation process on the scope and structure of the future declaration

Consultations started as early as possible. The purpose of the consultations was to explore ideas concerning the possible scope and structure of the future declaration prior to any effort to draft a text. Questions guiding the consultations related to the scope (Should the declaration be limited to human beings?), the content (Which fundamental principles should be reaffirmed? Should specific areas of application be included?), the structure, and the usefulness (How and at what level could the declaration contribute to better assessing the ethical implications of scientific progress and its applications?).

In November 2003, the Inter-Agency Committee on Bioethics met for the second time in Geneva, providing United Nations agencies and other intergovernmental organizations with an initial opportunity to exchange views. In December 2003 in Rome, there was an exchange with the Chairpersons of European national bioethics committees at a meeting held in co-operation with the European Commission. In January 2004, a written consultation with Member States was launched; 190 Member States, Associate Member States

and Permanent Observer Missions received a simple and concise questionnaire designed in consultation with the IBC Bureau inviting responses concerning (1) aims and scope, (2) the structure, and (3) the content of the declaration. At the end of April 2004 the Secretariat had received 67 official replies from Member States. The replies generally welcomed the drafting of a text that was broad in scope and not limited to human beings. The large majority of States were in favour of a structure comprising a preamble followed by sections. Among the fundamental principles most often cited by States were respect for human dignity, confidentiality, consent and transparency; some States also mentioned others, such as the right to life, the rights of the child, equity and tolerance. The vast majority of the replies suggested that the declaration should, as far as possible, make reference to specific subjects, although opinion was divided on certain subjects such as abortion, euthanasia, intellectual property rights and behavioural research. Nonetheless, it was highlighted in the general commentaries that, even if specific subjects were mentioned, the declaration ought to be one of general principles that could be the object of a large consensus and which could be applied to new scientific advances in the future (UNESCO, 2004a).

Consultations continued during the Extraordinary Session of IBC, which took place in April 2004 in Paris with 200 participants from more than 70 countries. The session was organized into hearings of representatives of three different groups:

a. intergovernmental organizations, such as FAO, WHO, the United Nations University, the Arab League Educational, Cultural and Scientific Organization (ALECSO), the Council of Europe and the European Commission;

b. international non-governmental organizations, such as the World Medical Association (WMA), the Human Genome Organization (HUGO), the International Council for Science (ICSU), Disabled People's International (DPI) and the International Association of Bioethics (IAB);

c. national bioethics committees, with oral presentations of representatives of such committees from Croatia, the Dominican Republic, Egypt, France, Japan, Korea, Mexico, New Zealand, Portugal, the Republic of Congo, the Côte d'Ivoire, the Russian Federation, Tunisia, the United Kingdom and the United States of America, while more than 15 other national bioethics committees and similar bodies also took part in the meeting.

The presentations were followed by an interactive question-and-answer session with IBC members and the audience. All organizations and institutions were invited to submit written contributions in advance, based on an outline structured around groups of questions, to provide IBC with a comprehensive overview of all the ideas and opinions expressed. The hearings offered an opportunity to clarify the views expressed in the written contributions received previously (IBC, 2004a).

In the same month, the timetable for drafting the future declaration was approved by the 169th session of the Executive Board (UNESCO, 2004b). Another important consultation process had been initiated one month earlier: called 'Ethics around the world', a set of rotating conferences for national consultations with experts. In co-operation with the National Commissions for UNESCO, IBC members and UNESCO's Secretariat, conferences were organized with experts in the Netherlands (March 2004), the Islamic Republic of Iran (May 2004), Lithuania (September 2004), Turkey (September 2004), Argentina (November 2004), South Korea (November 2004), Mexico (November 2004), Indonesia (December 2005), Portugal (January 2005) and the Russian Federation (January 2005). These conferences provided an overview of the opinions of people living in different cultural contexts. They also helped the Drafting Group to understand the cultural diversity.

2. The development of the preliminary draft

Completing the first phase of initial consultations, in April 2004 the IBC constituted a Drafting Group responsible for drawing up the preliminary draft. This group, chaired by Justice Michael Kirby, was initially composed of a limited number of IBC members but gradually expanded its membership during the drafting process (UNESCO, 2004c).

The group held its first meeting in Paris in April 2004. One of the issues raised concerned the title. Since the resolution of the General Conference employed the wording 'Declaration on universal norms on bioethics', it was agreed that this would be the wording to be used during the drafting process but would not necessarily be the title of the declaration. Another issue was the scope of the declaration. Given the limited time frame, the group decided to concentrate in the first place on the human being, while leaving open the possibility, if necessary, to refer to other fields and/or to cover them in the future. As regards the structure of the preliminary draft, all members of the group agreed that the draft should be constructed with a preamble, a section devoted to definitions if necessary, followed by

provisions concerning the objectives of the declaration, its scope, general principles, procedural principles and implementation. The content of the preliminary draft gave rise to extensive debate, first of all focusing on the connection between general principles and specific issues. For the time being, the group preferred to structure the declaration around general principles. As regards to the principles, several possible distinctions were discussed, but it was recognized that any hierarchical organization of principles should be avoided. Finally, it was discussed how to deal with specific issues, particularly controversial ones. The Drafting Group in this first meeting drew up a preliminary outline of the structure of the declaration (IBC Drafting Group, 2004a). This outline was circulated among all IBC members.

The second meeting of the Drafting Group in June 2004 in Paris produced the 'First Outline of a Text', taking into account the proposals received from members of IBC (IBC, 2004b). The discussions in the meeting centered on the principles to be included in the text. Obviously some bioethical issues are so controversial that a common position seems impossible to achieve. At the same time, there was the need to respect cultural diversity and plurality of viewpoints. Knowing that it was impossible to reconcile all those viewpoints, the declaration could certainly promote reflection and the search for common general positions. The term 'principles' in this respect was seen preferable over the term 'norms', used in the wording of the mandate. The group decided to distinguish between the general principles on the one hand and the application of principles and principles of procedure on the other hand (IBC Drafting Group, 2004b). The First Outline had an elaborated text of the 'Preamble', a section headed 'Use of Terms' (but the group decided to deal with this section later, if necessary at all), a first wording of 'Scope' (with a focus on the human being but recognizing the responsibilities and duties of human beings towards all other forms of life), a list of 'Aims', then a section on 'General Principles' with basic principles that should underpin every decision and practice in the field of bioethics, followed by brief sections with only bullet points for 'Application of the General Principles', 'Procedures', and 'Promotion and Implementation' (IBC, 2004b).

The First Outline was sent to all IBC members as well as members of the Inter-Agency Committee on Bioethics, who discussed the draft text during its third meeting later in June 2004 in Paris. It was also sent to members of the Intergovernmental Bioethics Committee (IGBC). An Information Meeting of the IGBC was held at UNESCO Headquarters, Paris, in July 2004 to inform IGBC of the work in progress on the elaboration

of a declaration on universal norms on bioethics and to exchange views on the First Outline (UNESCO, 2004d).

The third meeting of the IBC Drafting Group in July 2004, immediately after the above Information Meeting, elaborated the Second Outline (IBC, 2004c). This draft had more extensive sections on 'General Provisions' (including scope and aims) and 'Promotion and Implementation'. The central sections had been slightly reordered and renamed: 'General (or Fundamental) Principles', 'Implication of the General (or Fundamental) Principles', 'Specific Issues' and 'Procedures (or Procedural Principles)'. One discussion in the group concerned the title. Keeping the title as it had been worded in the resolution of the General Conference, the group decided to propose an alternative, in which 'norms' is not used and the word 'universal' is added to 'declaration' ('Universal Declaration on Bioethics and Humanity, or Humankind, or Human Beings'). The list of general principles was slightly adapted to include the principle of human dignity, human rights and justice; the principle of responsibility for the biosphere; the principle of beneficence; the principle of cultural diversity, pluralism and tolerance; and the principle of solidarity, equity and co-operation. The Second Outline also included a new section on Specific Issues, listing topics of bioethical debate, mostly taken from the IBC feasibility study of the previous year (IBC Drafting Group, 2004c).

The Second Outline was sent to all members of IBC in view of the 11th session of IBC that took place in Paris in August 2004 (IBC, 2004d). The session brought together 250 participants from 80 countries. An important part of the session was devoted to hearings of representatives of different religious and spiritual perspectives. Six speakers took the floor, respectively of the Buddhist, Catholic, Confucian, Hindu, Islamic and Jewish beliefs. Each speaker gave a presentation focusing on how their respective religious traditions viewed bioethics, and some commented on the text prepared by the Drafting Group. One lesson from the presentations and discussions was that although there are differing moral views, common values can be identified. It was also underlined that it was necessary to strike a balance between the principle of autonomy (emphasizing individual decision-making) and the place accorded to family and solidarity among human beings by particular religious and cultural traditions. The second part of the IBC session focused on examination and discussion of the Second Outline.

The IBC Drafting Group targeted its fourth meeting immediately after the 11th Session on the central sections dealing with the principles. It was decided to distinguish three categories of principles: (a) fundamental principles

are the basic principles that cannot be justified by any other principle and that belong to *jus cogens*, that is principles that cannot be derogated; (b) derived principles that can only be justified by one or more fundamental principles, without implying any hierarchy of these principles; and (c) procedural principles that describe the rules to follow and the framework to be put in place for the application of the principles, particularly when a balance needs to be found between the application of several principles that seem relevant at the same time (IBC Drafting Group, 2004d). Another important debate concerned the specific issues. Divergent opinions were expressed within the group. Some considered that the future declaration should be a text that proclaims general principles in the field of bioethics and that the examination of concrete subjects should be treated in other texts, taking into account the reports on specific issues already published by IBC. Without excluding the possibility of elaborating other texts at a later stage, other participants considered that if time did not allow for all specific subjects listed to be dealt with, the future declaration should nevertheless deal with central topics such as health and scientific research. This would allow an illustration of the application of the principles set forth in the declaration. On the basis of the discussions in the Drafting Group, the Third Outline of a Text could be finalized, with all sections elaborated except the one on specific issues (IBC, 2004e).

The Director-General presented at the 170th session of the Executive Board in October 2004 a report on the work carried out by UNESCO concerning the drawing up of a declaration on universal norms on bioethics. It contained in an annex the Third Outline of a Text (UNESCO, 2004c). Apparently, the Member States were satisfied with the progress made; in 2005 they decided to invite the Director-General to convene intergovernmental meetings of experts aimed at finalizing a draft of the declaration.

Later in October 2004, the Drafting Group held its fifth meeting in order to refine the text. In the meantime, a second written consultation of the Member States was started, based on this outline. Any modifications of the text would therefore have to be considered in the light of the results of this consultation. The result of the work of this meeting could therefore not be a new outline, but a modification of the existing outline. The group discussed sections that had not been discussed in the previous meeting: 'Preamble', 'General Provisions', and 'Promotion and Implementation'. One of the changes introduced in the text is the inclusion of definitions, for example of the term 'bioethics' ('the systematic, pluralistic and interdisciplinary study involving the theoretical and practical moral issues raised by the life sciences

and humanity's relationship with the biosphere') (IBC Drafting Group, 2004e).

Between October and December 2004 written consultations on the Third Outline were carried out among Member States, intergovernmental and non-governmental organizations, national bioethics committees and a number of eminent personalities. In early January 2005, 27 contributions from Member States and one response from a Permanent Observer, four contributions from intergovernmental organizations, 14 from non-governmental organizations, and institutes, 13 contributions from national bioethics committees and 10 contributions in a personal capacity had been received (UNESCO, 2005a). In December 2004 there was another occasion to discuss the outline with the relevant UN bodies and organizations during the fourth meeting of the Inter-Agency Committee on Bioethics.

The sixth meeting of the IBC Drafting Group took place mid-December 2004 and discussed the results of these consultations (IBC Drafting Group, 2004f). The group decided to reorganize the principles. The consultations showed that the distinction made in the text between 'fundamental principles' and 'derived principles', although appropriate from a theoretical point of view, is not common in a legal text and could lead to confusion as to a possible hierarchical organization of principles. The Drafting Group therefore decided to regroup them under a single section on 'general principles'. The principles were thus reorganized along the logic initially followed, that is first the principles relating to the individual, then the principles bearing on the relationship between human beings, and finally the principles concerning the relationship between human beings and other forms of life and the biosphere.

Another important issue was the principle of primacy of the human person. This principle is of paramount importance since it is closely linked to respect for human dignity and its aim is to avoid any abusive decision made in the name of society. However, in many cultural traditions, the family and the community are more important. The group decided to integrate this principle in the article on respect for human dignity. The primacy of the human person finds its limits in the principles of justice and solidarity. Due emphasis needs to be given to the term 'sole' (in Article 3.2 of the adopted text) which constitutes the balance of the formulation used.

The group furthermore took account of the concerns expressed throughout the different consultations as to the link between bioethics and global problems such as access to quality health care, nutrition, drinking water, poverty and illiteracy. Some felt that these questions constituted new

stakes for bioethics. In order to reflect this concern in the text, the group wished to further develop the idea of 'social responsibility', already broached in the Preamble. Aware of the innovative contribution of the declaration on this discussion, it was decided to introduce a new general principle entitled 'Social Responsibility'.

On the basis of these deliberations, the group finalized the Fourth Outline of the Text (IBC, 2004f).

This outline was subsequently presented to the 4th session of the IGBC in January 2005, immediately followed by discussion in the Joint Session of IBC and IGBC. The IGBC was satisfied with the improvements of the text. The Committee noted that 'many crucial issues and principles need to be considered further, including but not limited to those related to autonomy, informed consent, social responsibility, risk assessment, sharing of benefits, transnational practices and ethics committees', and invited IBC, in the framework of the finalization of a preliminary draft declaration, to reconsider the relevant articles. The Joint Session was followed by an Extraordinary Session of IBC, also in January 2005. In this Session, IBC carefully examined the numerous comments on the text and finalized and approved the Preliminary Draft Declaration on Universal Norms on Bioethics. This preliminary draft was published in February 2005 (IBC, 2005).

3. Finalization of the text

The Preliminary Draft Declaration approved by IBC after one year of intense work and six meetings of its Drafting Group, three sessions of IBC, two written consultations, numerous consultations at international, regional and national levels (including within the framework of the Inter-Agency Committee on Bioethics), a session of the IGBC and a joint session of IBC and IGBC was now in the hands of the Director-General of UNESCO, who submitted the draft to the Member States. Any normative instrument needs to reflect the scientific and ethical state of the art. But in the end it 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. This is not a choice of UNESCO, but in fact a statutory process required for any normative instrument. In order to finalize the draft declaration, the Director-General officially convened two meetings of governmental experts in April and June of 2005. Contrary to the IGBC (with 36 Member

States), experts from all Member States are invited to participate in such intergovernmental meetings.

The first intergovernmental meeting of experts aimed at finalizing a draft of the Declaration on Universal Norms on Bioethics was held at UNESCO Headquarters in Paris from 4 to 6 April 2005. Government experts from 75 Member States and 2 Permanent Observers participated in the meeting. Although the text was welcomed, some delegations expressed strong reservations with regard to the preliminary draft. The discussions first of all focused on the scope of the declaration. According to some participants, the field of application of bioethics had been considerably extended in recent years; although bioethics originally referred to ethical issues arising in the field of medicine and life sciences, over the past 10 years it had gradually encompassed ethical issues associated with the environment and the biosphere; it had acquired a particularly strong social dimension, notably in developing countries. Divergent points of view were expressed with regard to the definition of bioethics and to the use of this term in the framework of the declaration and with regard to its field of application. The meeting therefore wished to have a detailed discussion on the different perspectives of bioethics and on the way in which they could be reflected in the text. Differing views were expressed with regard to the nature of the bioethical issues that should fall within the field of application of the declaration. Some wished to limit the scope of the declaration to bioethical issues related to medicine and the life sciences, at the same time expressing the wish that the text acknowledge the link between the human being and the biosphere. Others felt that the social dimension of bioethics should be at the heart of the future declaration, the principles of which should apply not only to so-called 'emerging' issues, i.e. those linked to advances in science and the new technologies, but also to 'persistent' issues, i.e. those linked to development, poverty, public health, access to treatment and health care. Agreement on the definition of bioethics, however, could not be reached.

Controversies also emerged in relation to the language used in the preliminary draft. With regard to the use of the words 'shall' and 'should', some delegates considered that the non-binding nature of the declaration called for the use of the verb in the conditional form, since the text contained no formulation of an obligatory nature. Other delegates felt that the use of 'shall' in a declaration only indicated the moral commitment of States without contesting the non-binding nature of the text. Others felt that if the provision dealt with an obligation or a right already defined in other international instruments adopted by States, the use of 'shall' should be favoured, whereas,

if a new obligation seemed to emerge, the use of the word 'should' would allow for the nature of the declaration – where no new obligations can be created – to be respected. Several States proposed amendments of a textual nature and also of substance.

Within this context, the delegates could not engage in a drafting process. They felt that further in-depth discussions were necessary, notably on the issue of the scope of the declaration. The delegates therefore recommended to the Chairperson of the meeting that open-ended inter-sessional consultations between States on diverging views should be encouraged in order to prepare and facilitate the work of the second intergovernmental meeting of experts in June 2005 and, on these occasions, that the Chairperson should play the role of facilitator between the different parties. In order to be able to finalize a draft declaration for the 33rd session of the General Conference, the meeting also considered it essential to have additional time at the June 2005 meeting, with the availability of documents and interpretation in all official languages of the Organization (Report expert meeting, 2005a).

A few weeks later in April 2005, the 171st session of the Executive Board discussed the progress report of the Director-General and decided that 'the government experts, at the meeting in June 2005, should prepare and present a draft to the Director-General in view of its transmission to the General Conference at its 33rd session in October 2005' (UNESCO, 2005b: 2).

In the meantime, the Chairperson of the intergovernmental meeting, Pablo Sader, the Ambassador of Uruguay to UNESCO, was active in conducting informal consultations with some Member States. On this basis he prepared a so-called 'non-paper' with his thoughts and questions, which was distributed among all delegations. He then proceeded to invite the Permanent Delegations at UNESCO to participate in an Informal Meeting on 17 May 2005 in order to pursue the discussions already undertaken during the first meeting on fundamental issues. In his 'non-paper' he identified the following issues: (1) use of terms and scope (Which notion of bioethics should be applied in the declaration?), (2) aims (To whom is the declaration addressed: States, institutions, individuals?), (3) principles, and (4) transversal and other issues (e.g. human beings/human persons, the formulation 'any decision or practice', 'shall' and 'should'). The Chairperson also suggested solutions and compromises for the issues at stake (Chairperson, 2005).

The Informal Meeting with the Permanent Delegations organized by the Chairperson of the intergovernmental meeting took place on 17 May 2005. Eighty participants from 55 Member States took part. The

Chairperson pointed out that the meeting should not be considered as a negotiation meeting, but rather as an opportunity for free and open discussion; the results of the meeting, albeit indispensable, would remain informal and would facilitate negotiations during the intergovernmental meeting of experts in June. During that meeting, it was discussed how an academic definition of bioethics could be avoided by providing a description of bioethics in the field of application of the declaration. About the provision on the scope three elements were mentioned: the medical and health aspect, covering issues raised by the ethics of medicine, life sciences and their applications and biomedical research; the social aspect, including access to health care and treatment; and the environmental aspect, particularly in terms of responsibility of the human being towards other forms of life and the biosphere. Concerning the recipients of the declaration, the participants were unanimously in favour of explicit identification of States as the first recipients, without excluding all the other actors concerned for whom the declaration should constitute a document that could provide guidance in their decisions and practices. Generally speaking, the participants expressed their satisfaction with the section devoted to principles. Concerning the use of 'shall' and 'should', it was suggested to use 'should' as a general rule and 'shall' for the provisions that aim at reaffirming in the context of bioethics the rights and obligations already established in the international law of human rights. As to the use of 'human being' or 'human person', while 'human being' appeared to be acceptable to all, its use should be examined on a case by case basis, as was suggested for the formulation 'any decision or practice'. As to the title of the declaration, a clear preference emerged to include the mention of human rights. The Chairperson concluded that the meeting had been conducted in a spirit of constructive and productive co-operation and had allowed to pave the way towards consensus on a number of issues (Informal meeting, 2005).

The second session of the intergovernmental meeting of experts took place from 20 to 24 June 2005 in Paris. Experts from 90 Member States participated. The meeting proceeded with an article-by-article examination of the Preliminary Draft Declaration finalized by the IBC. At the suggestion of the Chairperson, the discussions and drafting process were carried out in plenary and, when the need arose, informal groups were constituted in order to facilitate the work in plenary. Regarding the terms 'decision or practice' it was decided to include, at the beginning of the chapter devoted to principles, a heading that refers to decisions or practices taken or implemented by recipients in the field of application of the declaration and to reformulate

the provisions in an impersonal manner by directly stating the principles. Concerning the scope, there was a preference to merge Articles 1 and 2 into a single article focusing on the scope of the declaration and to define 'to what' and 'to whom' the declaration applies, thus avoiding entering into a detailed definition of bioethics. Concerning the aims, delegates decided to make a distinction between two paragraphs; that is the first underlining the aims of the declaration with regard to States, and the second devoted to individuals, groups, communities, institutions and corporations, public and private, whose actions the declaration would aim to guide.

Examining the principles, an intensive discussion was devoted to the article on informed consent, underlining the importance of consent in bioethics. Some delegates express the wish to further develop the provision concerning persons incapable of expressing their consent. An informal group was established by the Chairperson; the group formulated two articles that were approved by the meeting. The first article deals with the conditions required for consent, on one hand, with regard to preventive, diagnostic and therapeutic medical intervention, and, on the other hand, with regard to scientific research. A separate paragraph of this article addresses consent in the context of research carried out on a group of persons or a community. The second article is devoted entirely to persons incapable of giving consent.

The article on social responsibility also raised the interest of the intergovernmental experts. Numerous delegates, particularly representatives of developing countries, reiterated the paramount importance of this article, which would allow for the social aspect of bioethics to be reflected in the declaration. They felt that this provision should also aim at a specific recognition of the right to health and at the affirmation of the promotion of health and social development as principles that should be applied by all, in particular by States. After some negotiation, a consensual text was adopted in a constructive spirit of compromise. Many delegates nevertheless regretted that the reference to reproductive health no longer appeared in the approved formulation.

At the suggestion of some countries, two new principles were added: one concerning the protection of future generations, and the other related to respect for vulnerability in order to give special attention to persons and groups in vulnerable situations.

There was also a debate on the article on risk management. Several delegates felt that this provision did not come within the field of application of the declaration, while others argued, on the contrary, that it was important to provide an ethical framework to assess and manage risks in the field of

medicine, life sciences and associated technologies. The meeting decided to retain the article by amending it in such a way as to formulate a general principle without going into a detailed explanation.

Finally, the intergovernmental experts decided to adopt the title as proposed by the IBC: 'Universal Declaration on Bioethics and Human Rights'. In concluding their work, the States represented at the second session of the intergovernmental meeting of experts adopted the Draft Universal Declaration on Bioethics and Human Rights for presentation to the Director-General, followed by its transmission to the General Conference in October 2005 (Report expert meeting, 2005b).

At its 33rd session, the General Conference of UNESCO adopted by acclamation the Universal Declaration on Bioethics and Human Rights on 19 October, 2005.

THE CONTENT OF THE NEW DECLARATION

One of the contentious issues in the elaboration was the scope of bioethics. As mentioned earlier, at least three views were advanced: 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 pragmatic 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' (Article 1.1).

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' (Article 2(a)). One characteristic of present-day bioethics is that it is not only an academic discipline; it is also an area of public debate and policy-making. This is why the Declaration is primarily addressed to States. But at the same time, since the bioethical principles identified are founded on human rights and fundamental freedoms, every individual is concerned by bioethics. The Declaration, therefore, also aims 'to guide the actions of individuals, groups, communities, institutions and corporations, public and private' (Article 2(b)).

The heart of the Declaration is to be found in the 15 principles (Articles 3 to 17). 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 listed in the new declaration is the balance struck between individualist and communitarian moral perspectives. The Declaration recognizes the principle of autonomy (Article 5) as well as the principle of solidarity (Article 13). It emphasizes the principle of social responsibility and health (Article 14), which aims at re-orienting bioethical decision-making towards issues urgent to many countries (such as access to quality public health and 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 (Articles 18 to 21) is 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.

QUESTIONS

Published in the six official languages of UNESCO, the Universal Declaration on Bioethics and Human Rights is increasingly the subject of discussion, analysis and reflection. The questions raised in the literature can be categorized around several issues of concern: (1) the role of intergovernmental organizations; (2) the need for international standard-setting; (3) the nature of the text; (4) the connection of bioethics and human rights; (5) the relationship

between global bioethics and cultural diversity; and (6) the effects of the Declaration (ten Have, 2006b).

1. The role of intergovernmental organizations

Concerns have been raised about the involvement of intergovernmental organizations in bioethics. In the UN system several specialized agencies are active in bioethics: the FAO has a programme of addressing the ethics of food and agriculture, WIPO is concerned with the ethical issues related to intellectual property rights and patenting, and WHO with the ethics of medical research and practice. For this reason, as mentioned above, the Director-General of UNESCO has taken the initiative to establish the Inter-Agency Committee on Bioethics in order to enhance coherence and co-operation and avoid duplication. Rather than meddling in each others' domains, the UN agencies are co-operating (Landman and Schuklenk, 2005). UNESCO, WHO and other specialized organizations in the UN system are organizations of Member States. They decide the budget and the scope of activities. It is up to them to decide which organization should deal with bioethics. They have, for example, decided to bring the issue of human cloning to the General Assembly in New York, which, after political negotiations, adopted the UN Declaration on Human Cloning early in 2005. For more than 10 years, however, the Member States of UNESCO have been supporting and expanding the programme in bioethics. They have good reasons for doing that. Bioethical issues are often strongly connected with science and technology. The emergence of bioethics since the 1960s is associated with the rise of the life sciences. As the only UN specialized organization with a mandate in science, UNESCO started to reflect on the ethical implications of the life sciences in the 1970s. Bioethics also has implications for the education of future scientists and health care professionals, and bioethics has its roots in cultural traditions. Bioethics therefore differs from medical ethics, precisely because it has a wider scope and raises wider concerns. Ethical issues are nowadays important for every citizen, and neither medical professionals nor scientists can decide alone what is morally desirable, since bioethics in a globalized and culturally diverse world concerns the common good (Cahill, 2004; Jean and Godard, 2008). The general nature of bioethics therefore supports the view that it should be addressed by an organization with a broad mission in science, education and culture. This argument is linked to another one: in agencies like FAO, WHO and WIPO, bioethical issues are addressed from a specialized point of view; they are relevant as far as they are

related to the mission of the agency. UNESCO, as an agency with a broader perspective, can take into account the full range of bioethical issues from a policy-making point of view.

Finally, a practical argument for situating bioethics in UNESCO is of course past experience (Andorno, 2007). The experience gained in drafting and negotiating two declarations in this domain, the expertise brought together in the IBC, as well as the mechanisms of interplay between scientific experts and intergovernmental experts have undoubtedly played a major role in the decision of Member States to request the Director-General of UNESCO to develop a declaration covering the whole domain of bioethics.

2. The need for international standard-setting

A second type of question is related to the international standard-setting activity. With so many documents already available, the question has been raised about the real contribution of the Declaration (Macklin, 2005). It is also argued that universal declarations are necessarily vague and minimalist; they will therefore not provide much guidance because everyone can interpret the text as he or she likes (Benatar, 2005). On the other hand, it has been pointed out that the Declaration is significant because of its stature as an international declaration issued by a United Nations organization (Macklin, 2005). There are many international documents in bioethics, sometimes very well known and influential, such as the Declaration of Helsinki, adopted by the World Medical Association, but the Universal Declaration on Bioethics and Human Rights is the only one adopted by governments. It presents principles and applications of principles to which governments have committed themselves. It is therefore a relevant frame of reference for future developments in bioethics, especially since all governments have unanimously agreed with this text. The Declaration furthermore reflects a truly global perspective on bioethics, taking into account the many cultures, traditions and schools of thought within the Member States. Perhaps this shows the primary advantage of the United Nations: providing a platform, bringing together all countries, and enabling them to discuss the values they share and to agree on what should be done for all citizens of the world.

It should be stressed that the Declaration will be most useful for countries that lack an infrastructure in bioethics rather than for countries that already have extensive legislation, bioethics expertise and committees. The need for international standard-setting in bioethics has therefore been more strongly expressed by developing countries who want to share the

benefits of the developments of science and technology and not only be the providers of data and resources. They want to be sure that the advantages and disadvantages of scientific development and technological innovation are equally and equitably shared among all nations. They want to guarantee that the standards and regulations concerning bioethical issues reflect a global perspective beyond national and regional interests and concerns. But of course there is a long way to go. The UNESCO Declaration is a first step: it provides a framework of general principles that is open to various interpretations and applications in the context of human rights and fundamental freedom, leaving many specific issues and controversies open for further debate.

3. The nature of the text

The nature of the text is sometimes misunderstood (e.g. Macpherson, 2007). The Universal Declaration on Bioethics and Human Rights is necessarily the result of compromises, which is a normal way of proceeding in any international negotiation between different cultures, religious traditions and political views. The preliminary text has been drafted by scientific experts in the IBC, but even they had to make compromises among themselves. The ultimate decisions regarding the text have been made by governmental experts. This linkage between science and politics is one of the characteristics of an intergovernmental organization. This gives strength to the text since it now represents the views of all governments going beyond the perspectives of scientists and individual experts. It can at the same time be a weakness because political rationality is different from scientific rationality. The logical structure and argumentation provided by the scientific experts can be changed during the political negotiations. This was of course the case in the drafting process of the Declaration. However, comparing the various outlines of the draft at various stages of development (all materials are on the UNESCO web site and have been publicly accessible through all stages), it can be said that the changes made have not fundamentally transformed the preliminary draft provided by the IBC.

4. Human rights

One of the new elements of the Universal Declaration on Bioethics and Human Rights is that it connects bioethics and human rights (Andorno, 2007). International documents such as the European Convention on Human Rights and Biomedicine and the Declaration of Helsinki refer to human rights (and human dignity). In the same vein, the UNESCO Declaration

continues to invoke 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 (Faunce, 2005; Nys, 2006).

5. Cultural diversity

Questions have also been raised about the relationship between universal and culture-related values (Benatar, 2005; Jing-Bao, 2005). It is argued that the Declaration, for example in Article 3, gives primacy to individual interests. Examining the whole range of principles, however, it is remarkable that agreement was reached on a set of principles much broader than the individually orientated ones. As demonstrated above, the principles of the Declaration cover a range of moral objects, from the individual human being itself to other human beings, to human communities, to humankind as a whole, and to all living beings and their environment. It is true that there is no hierarchy among the diverse principles. Article 3 nonetheless is remarkable since is has a wording similar to that found in other documents (such as the Declaration of Helsinki). The key word in fact is 'sole'; if society is seriously threatened, for example, by a pandemic, individual interests can be restricted, as expressed in Article 27. Still, it has to be seen whether the right balance has been struck between universal human values and cultural difference.

6. Effects

From the perspective of international law it is clear that a declaration adopted in the UN system is not a binding instrument. Nonetheless, the history of human rights demonstrates that what starts as soft law (e.g. the 1948 Universal Declaration of Human Rights) can in time obtain a wider context. As Faunce (2005) and Macklin (2005) have pointed out, the UNESCO Declaration may in future lead to the drafting of an international bioethics convention. It may also become an incentive for other legal initiatives, such as the drafting of regional conventions, following the example of the Convention on Human Rights and Biomedicine adopted by the Member States of the Council of Europe in 1997 (Lenoir and Mathieu, 2004). It is important to note that the Universal Declaration on Bioethics and Human Rights has already been cited as a relevant international text in the recent judgment

of the European Court of Human Rights in the Case of Evans versus the United Kingdom (2006).

It is of course one thing to solemnly agree on the text of a declaration, but quite another to bring it into practice (Schmidt, 2007). However, it is significant that the governments adopting the principles have in the same declaration also adopted sections on the application of the principles and promotion of the Declaration. Member States have thus committed themselves, amongst others, to encourage the establishment of ethics committees, to foster information and knowledge dissemination, education and training at all levels and to promote bioethics education.

FOLLOW-UP OF THE DECLARATION

It is significant that all UNESCO Member States 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 international documents adopted by non-governmental organizations do not create the same commitment on the part of governments.

Furthermore, the new Declaration is the beginning rather than the end of a process of internationalization of bioethics. Present-day bioethics are not cast in stone; rather they are evolving. Special attention therefore needs to be given to the application of the principles and to the dissemination and promotion of the Declaration. Member States that have not already done so are encouraged 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.

As of today, it should be mentioned that UNESCO has initiated a range of activities to promote the application of the principles of the Declaration in the Member States.

1. Promotion and dissemination

It is of course necessary, first of all, to disseminate information concerning the Declaration and to make its text known and available in all Member States. Up to now, the Declaration has been translated into approximately 30 languages. This will facilitate the use of the Declaration in universities, research centers and schools. UNESCO has also made available various formats of the Declaration. Contributions have been made to publications

in journals and web sites. Several books on the Declaration have thus far been published (see list at the end of this volume).

2. The Global Ethics Observatory (GEObs)

First, the Global Ethics Observatory (GEObs) was set up to provide data concerning ethics experts and institutions, committees and societies in all UNESCO Member States, as well as to provide detailed information concerning existing ethics teaching programmes (ten Have and Ang, 2007). At this point in time, groups of legal experts are developing materials and data to build a comparative international database of legislations and guidelines in the domain of bioethics, related to the principles of the Declaration and areas of debate in bioethics (Ang, ten Have, Solbakk and Nys, 2008).

3. The Ethics Education Programme (EEP)

To promote the teaching of bioethics, several interconnected activities have been put in place (ten Have, 2008). First, experts with ethics teaching programmes are identified and invited to describe these programmes in detail. Regional meetings bring the experts together to discuss and analyze the information. Meetings have already taken place in Budapest (Hungary, October 2004), Moscow (Russian Federation, January 2005), Split (Croatia, November 2005), Tehran (Islamic Republic of Iran, October 2006), Muscat (Oman, November 2006) and Istanbul (Turkey, March 2007). More than 170 teaching programmes from 20 countries are now available in the GEObs database on ethics teaching. A second activity is the development of a proposal for a core course in bioethics, based on the Declaration. This proposal, advocating a multicultural basic course, will be tested in universities in 2008 and 2009. Third, UNESCO is offering a training course for ethics teachers in order to help create a new generation of teachers. Courses have been held in Romania (November 2006), Kenya (July 2007), Slovakia (September 2007) and Saudi Arabia (November 2007). Finally, UNESCO is collecting and providing educational resources, for example international case books in co-operation with the UNESCO Chair in bioethics in Haifa, Israel.

4. The Assisting Bioethics Committees project (ABC)

This project has three stages: first, fact-finding by identifying existing ethics committees and collecting data (in Global Ethics Observatory Database 2); second, providing practical information concerning the establishment of

ethics committees (UNESCO, 2005d), the work methods and procedures of committees (UNESCO, 2006) and education of committee members (UNESCO, 2007b); third, providing technical support. Task forces of experts from countries having built an experience with their own national bioethics committees (e.g. France, India, Mexico, Saudi Arabia) are offering technical assistance to countries wishing to establish such committees. During 2007, technical missions were carried out in Gabon, Ghana, Jamaica, Madagascar, Malawi, Mauritius and Togo. Once a national bioethics committee has been established, a co-operation agreement between the committee and UNESCO is signed in order to make the committee sustainable through training, documentation, secretarial expertise and networking. New national ethics committees have so far been inaugurated in Gabon, Ghana, Madagascar and Togo (UNESCO, 2008).

5. Elaboration

The IBC contributes to the promotion and dissemination of the Declaration by pursuing reflection on the principles set forth therein. The Committee first reflected on the principle of consent (as formulated in Articles 6 and 7), and the report on this principle was submitted to the Director-General. It also started to reflect on the principle of social responsibility and health. This is a relatively new principle in bioethics, and the elaboration by the IBC will contribute to the dissemination and application of this principle in various settings. The IBC will complete and finalize its report on this subject in 2009. Most recently, the Committee has started to focus on the principle of respect for human vulnerability and personal integrity, as set forth in Article 8 of the Declaration.

International organizations such as UNESCO will continue to assist countries in developing and reinforcing 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 through two separate fields of discourse. Relevant basic principles have been promulgated in the health sciences and also in legal rules expressing basic civil rights. The great merit of the Universal Declaration on Bioethics and Human Rights is that it brings these two streams together; it does so at a global and universal level accepted by 191 nation states; and it places the combined statement in a wider setting concerned with the protection of

future generations of human beings and of the environment and biosphere, thus covering all living things. Let us express the hope that those concerned with bioethical questions everywhere will rise to its challenge.

THIS VOLUME

In order to contribute to the debate regarding the Universal Declaration on Bioethics and Human Rights, this volume offers article-by-article descriptions and commentaries. It is clear that the contributions do not in any way represent the views of UNESCO but only reflect the ideas of the authors. Most authors have been actively involved in the process of developing and drafting the Declaration as IBC members, governmental experts, delegates, and participants in hearings and meetings. In order to maximize the coherence of the contributions, the editors have asked the authors to address in their contribution three questions:

(1) Why is this article in the text of the Declaration? Answering this question will require an overview of the historical background as well as the reasons why this article has been included in the text of the Declaration. Another important question is how the current text evolved throughout the various discussions and stages of the drafting process. The elucidation of the background and evolution is greatly facilitated by the fact that the drafting process of the Declaration has been transparent and that all relevant documents are publicly available on UNESCO's web site.

(2) What does the article mean in the context of the Declaration? Addressing this question calls for a discussion on questions such as: how can the text of the article be explained by its history? How can the text of the article be explained within the context of the whole Declaration, previous declarations, other relevant texts and the bioethical literature? What is provided here is not an authoritative interpretation but an elucidation of the motives, reasons and arguments that have been used in the drafting process and that can plausibly demonstrate that the wording of the text has been chosen after much reflection and meaningful deliberations.

(3) How can the article be applied? The text of each article of the Declaration is brief and general. It is not always clear how the article can be used. Questions will be discussed such as: What is the potential usefulness of the article in bioethical debates related to challenging

and complex issues? How can the article be used in various contexts of application? Can examples be provided of possible applications?

As the reader will notice, the authors have largely followed the proposed framework, although in different ways. Not all articles required extensive elaboration and discussion. What all the contributions show, however, is the internal coherence of the articles, as well as the pondering, analysis, reflection and negotiations that have led to the final text of the Declaration.

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Chapter 2

THE PREAMBLE

Héctor Gros Espiell

BACKGROUND

The study of the structure, content and meaning of the Preamble of this Declaration adopted by acclamation at the General Conference of UNESCO on 19 October 2005 has first to refer broadly to the preambles of declarations adopted by the General Assembly of the United Nations, the General Assemblies or the General Conferences of specialized bodies of the United Nations or by organizations resulting from regional agreements foreseen in the Charter of the United Nations (Articles 57 and 52).

Indeed, before studying the preamble of a particular declaration, it is necessary to determine the legal nature, the meaning, the scope and the importance that preambles have on the interpretation of international declaratory instruments produced by these international organizations.

The presence of a preamble before the resolution section in the international declarations mentioned above is one of their characteristics. There has been practically no exception since the practice has existed of adopting these declaratory texts by acclamation, although it had not specifically been foreseen in the Charter. This practice has imposed itself in the United Nations and other regional organizations since the Charter of the United Nations came into force, even if some precedents are known.

The study of the meaning, the legal nature, and the importance of preambles as interpretative elements has been made by principally referring to the preambles of the Charter of the United Nations (Cot and Pellet, 2005; Kelsen, 1950; Jiménez de Aréchaga, 1958) and international treaties (Torres del Monte and Tejada, 2001; Rousseau, 1970). This has been the case for treaties creating regional organizations (for example, the Preamble of the Charter of the Organization of American States, 1948; and the Preamble of the Charter of the Organization of African Unity) and specialized bodies of the United Nations family (see, for example, the Preamble of the Constitution of UNESCO; Cowell, 1966; Mac Leish, 1985) and international bilateral or

multilateral conventions of all sorts, including those concerning human rights. On the other hand, and in general, this study does not refer to preambles of declarations emanating from universal or regional international bodies and intergovernmental organizations. However, there are some rare but valuable studies on the Preamble of the Universal Declaration of Human Rights (Martenson, 1992; Gutiérrez, 1979) and the Preamble of the American Declaration of Rights and Duties of Man (Gros Espiell, 1989).

The presence of preambles in these types of declaratory international instruments proves to be a constant characteristic in international law.

In fact, all declarations within the United Nations or regional organizations since the creation and the development of the current international system after the Second World War have a preamble.

If we restrain ourselves to the Declaration on Human Rights proclaimed on 10 December 1948, we have a determining example of this culture of preambles as we have a long series of posterior declarations that generally precede treaties or conventions. In the regional context, we will recall the first of those declarations, the American Declaration of Rights and Duties of Man (1948), proclaimed a few months before the Universal Declaration and introduced by an inspiring and moving preamble.

The relation between bioethics and human rights presents a similar scenario in the following declarations: the Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003), and the Universal Declaration on Bioethics and Human Rights (2005).

The preamble, whether it is of a conventional or a declaratory nature, forms part of an international instrument. This means that it forms part of a legal text. The declaratory part and the resolution part together constitute '*the context*' of the document, as stated by Article 31 of the Vienna Convention on the law of treaties.

This is why we cannot deny the legal nature of the preamble. But having a legal nature does not imply that it is inherently normative.

This means that States cannot derive any mandate or obligation directly from the preamble. However, because of its intrinsic legal nature, a preamble must be used to determine the ultimate aim of the instrument (the declarations) to guarantee its meaning, presentation and interpretation. The principle of having a preamble and a resolution section in the integral text ensures that it is read and interpreted its proper context, and this is applicable to the interpretation of treaties, conventions and declarations.

It would be a serious mistake to negate the legal nature of preambles by confounding the legality that is inherent to them with normative rules which, on the contrary, they are devoid of.

DEVELOPMENT OF THE PREAMBLE

The Preamble of the Universal Declaration on Bioethics and Human Rights is the outcome of a long process of elaboration of the Drafting Group of the IBC, the deliberations of plenary sessions of the Committee, the contribution of the IGBC and the meetings of governmental experts.

At each step, the necessity of having a preamble has been maintained and there was no significant opposition to it or any proposal for its suppression. This culture, unanimously approved, of structuring declarations of international organizations into two parts – the preamble and the resolution section – has therefore been maintained.

Since the beginning of the process of drafting the Declaration, the Drafting Group considered including a preamble (IBC Drafting Group, 2004a). During the first session of the Drafting Group's meeting (30 April 2004), I was given the responsibility to make the first draft of the future preamble. During this meeting, it was mutually agreed that the preamble would contain references to 'international instruments, agreements and existing guiding principles from the United Nations systems and other organizations' and a 'philosophical, scientific and political context' (IBC Drafting Group, 2004a, Annex p. 1). The analysis of the text of the preamble proceeded during the third meeting of the Drafting Group (8–9 July 2004) (IBC Drafting Group, 2004b). The Drafting Group included the project of the preamble (analyzed during its previous meetings) in the report of its fourth meeting (IBC Drafting Group, 2004c). An interesting debate on the necessity of having a preamble consisting clearly of inspiring acclamatory elements, intended for the general public, took place during the 11th Session of the International Bioethics Committee (IBC, 2004). The preamble draft was discussed and revised during the fifth meeting of the Drafting Group (IBC Drafting Group, 2004d). At the outcome of the sixth meeting (IBC Drafting Group, 2004e), the drafting team introduced the new preamble in the fourth draft of the text. The issue of a preamble was also addressed during the session of the International Bioethics Committee in January 2005 (IBC, 2005). The preamble was studied afterwards during the meeting of intergovernmental experts to develop a declaration relative to the universal norms of bioethics. The report of the second session of this intergovernmental

experts' meeting (20–24 June 2005) contains a reference to the issue of the preamble and to minor modifications introduced in the draft text (Report expert meeting, 2005). The preamble issue was also considered during the IGBC meeting and in one of the joint sessions with the Intergovernmental Committee on Bioethics (January 2005) (Joint Session, 2005). At the end of this complex drafting process, the General Conference adopted the Universal Declaration on Bioethics and Human Rights as well as the preamble defined by the numerous drafting steps previously mentioned.

Finally, since there has never been a proposition against the idea of having a preamble, the Declaration has been enriched by the legal instruments mentioned in the Preamble, and by the Preamble's acclamatory nature and its ethical, scientific and political foundations.

It should be noted that during the elaboration of the Preamble, the amendments and additions of the first draft followed two fundamental principles: expansion and diversification of the list of international instruments mentioned, and emphasis on the development of the preamble part intended to proclaim ethical, philosophical, scientific and political principles aimed not only at States but also addressed to the general public and to humanity and thus the international community.

EXPLANATION OF THE PREAMBLE

The Preamble is broader than in the two previous UNESCO bioethics declarations: The Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data.

This broadening can be explained by the fact that since the beginning of the elaboration process, the Drafting Group has tried to enunciate as many references as possible, directly or indirectly, to international instruments, and to add an evocative, supporting, promotional and inspiring acclamatory section that, following the preambles of the United Nations Charter, the Constitution of UNESCO and the Universal Declaration of Human Rights, focuses on human, scientific and international aspirations.

This was the case for the Preamble of the 1997 Universal Declaration on the Human Genome and Human Rights. The final paragraph of its Preamble reads as follows:

> *Recognizing* that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but *emphasizing* that such research should fully respect human dignity, freedom and

human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics.

Several paragraphs in the International Declaration on Human Genetic Data express similar ideas:

Recognizing that genetic information is part of the overall spectrum of medical data and that the information content of any medical data, including genetic data and proteomic data, is highly contextual and dependent on the particular circumstances,

Also recognizing that human genetic data have a special status on account of their sensitive nature since they can be predictive of genetic predispositions concerning individuals and that the power of predictability can be stronger than assessed at the time of deriving the data; they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group; they may contain information, the significance of which is not necessarily known at the time of the collection of biological samples; and they may have cultural significance for persons or groups,

Emphasizing that all medical data, including genetic data and proteomic data, regardless of their apparent information content, should be treated with the same high standards of confidentiality,

Noting the increasing importance of human genetic data for economic and commercial purposes,

Having regard to the special needs and vulnerabilities of developing countries and the need to reinforce international co-operation in the field of human genetics,

Considering that the collection, processing, use and storage of human genetic data are of paramount importance for the progress of life sciences and medicine, for their applications and for the use of such data for non-medical purposes,

Also considering that the growing amount of personal data collected makes genuine irretrievability increasingly difficult,

Aware that the collection, processing, use and storage of human genetic data have potential risks for the exercise and observance of human rights and fundamental freedoms and respect for human dignity,

> *Noting* that the interests and welfare of the individual should have priority over the rights and interests of society and research.

Five sections can be observed in the Preamble of the Universal Declaration on Bioethics and Human Rights.

The first section is composed of four paragraphs and constitutes the conceptual reflection on the relation between bioethics, science and technology and refers to human rights, human dignity, ethics and justice while taking the environment into account.

The second consists of three paragraphs and lists the international instruments considered in the Declaration.

The third, with only one paragraph, recalls the necessity to deal with the Declaration in a way compatible with national and international law and conform with human rights.

The fourth section consists of 11 paragraphs and is conceptually complementary to the first one and develops the foundation, the aim and the finality of the Declaration.

Finally, the fifth section announces that the General Conference 'proclaims the principles that follow and adopts the present Declaration'. This is an expression analogous to the Universal Declaration of Human Rights of 1948 where the General Assembly 'proclaims the present Universal Declaration of Human Rights' and to the Universal Declaration of the Human Genome and Human Rights adopted by the General Conference of UNESCO in 1997, which 'proclaims the following principles and adopt the present declaration'.

Therefore, to specify the importance and the significance of the Universal Declaration on Bioethics and Human Rights adopted on 19 October 2005, the General Conference not only adopted the Declaration but also proclaimed its list of founding principles.

The first part explains the reason, the basis and the necessity of adopting the Universal Declaration on Bioethics and Human Rights and explains the universal principles – referring to the capacity of reflection of human beings and the consequences of the rapid evolution of science and technology.

These four paragraphs state:

> *Conscious* of the unique capacity of human beings to reflect upon their own existence and on their environment, to perceive injustice, to avoid danger, to assume responsibility, to seek co-operation and to exhibit the moral sense that gives expression to ethical principles,

> *Reflecting* on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,
>
> *Recognizing* that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,
>
> *Resolving* that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for humankind and for the environment,

The second part of the Preamble is dedicated to the list of diverse international instruments that are directly or indirectly linked to bioethics. The instruments of this list are of different and diverse nature: 'conventional and declaratory', 'universal and regional' emanating from the United Nations, specialized bodies of the United Nations system, other intergovernmental organizations as well as scientific and non governmental organizations. Furthermore, paragraph eight of the second part of the Preamble transits from international to national law by making provisions for local bioethics legislation.

This list of instruments of diverse origin and nature, unfamiliar to the United Nations system, is an innovation in the legal culture of UNESCO (UNESCO, 2005).

This illustrates the recognition and demonstration of the existence of a 'law of the international community and humanity and the oneness and universality of the legal order' and the essential roles of all parties. This law is not divisible and cannot be arbitrarily separated within independent non-communicating systems.

The list of these numerous texts does not mean that a stand has been made concerning their legal value and is not aimed at formulating criteria about their respective legal hierarchies and forces.

There is no need in this text to list all the instruments mentioned in the Preamble.

The third part, as stated before, has only one paragraph. The paragraph which reads as follows '*Recognizing* that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law' is of particular importance. In fact, it sets the conditions

for the necessary compatibility of national and international law in the understanding, interpretation and application of the Declaration. Referring to international law and not solely to national law is very important because of the progress of the former in bioethics. Referring to the two laws questions the hierarchical relationship between the two normative systems and the place of international law in national legal systems.

Finally, the specific reference to the 'law of human rights' as an autonomous, distinct and legal discipline pertaining to human rights encloses systematically national and international law.

The fourth section constitutes an extension of the first. It extends and applies themes and specific questions characterized mostly by current events and their increasing human, social and cultural incidences, starting from the same criteria developed in the first four paragraphs. This section of the Preamble is particularly important in the interpretation of the articles of normative nature relating to the same subjects in the acclamatory section.

As for what can be considered as the fifth part of the Preamble, I have already highlighted the meaning that needs to be attributed to the statement 'adopting' the present Declaration and 'proclaiming' the principles that the Declaration lists.

APPLICATION

All the previous arguments highlight the significance of the Preamble in the application, the interpretation and the future of the Universal Declaration on Bioethics and Human Rights.

This Preamble, comprising the conceptual and acclamatory part that defines the objective and the finality of the Declaration and the listing of instruments related to bioethics, is very important and has to be highlighted.

Moreover, this importance arises firstly from the fact that the Universal Declaration on Bioethics and Human Rights has to be understood, interpreted and applied systematically with the two other internationally adopted instruments of UNESCO: The Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data.

Secondly, in the absence of an exhaustive list of questions and problems posed by bioethics today, this Declaration is open to the future. It has to be perfected and completed in the future by continued emphasis on proclaimed principles, declared objectives and invoked rights. It is this characteristic of the Declaration that depicts the importance of the Preamble.

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Chapter 3

ARTICLE 1: **SCOPE**

Michael Kirby

Article 1 – Scope

1. *This Declaration 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.*
2. *This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practises of individuals, groups, communities, institutions and corporations, public and private.*

DRAFTING HISTORY

Article 1 underwent comprehensive change at several stages during the drafting process of the Declaration. The evolution of the text of this Article provides a critical insight into the overall development of the Declaration and the intended meaning of the Article in its final form.

There were six official drafts of the Declaration prepared by the IBC Drafting Group prior to the adoption of the final text by the 33rd session of the General Conference of UNESCO in October 2005. A brief chronology of these drafts follows:

30 April 2004	Draft outline of the structure of the Declaration finalized by the IBC Drafting Group
15 June 2004	First draft finalized by the IBC Drafting Group
27 July 2004	Second draft finalized by the IBC Drafting Group
27 August 2004	Third draft finalized by the IBC Drafting Group
15 December 2004	Fourth draft finalized by the IBC Drafting Group
9 February 2005	Preliminary Draft Declaration finalized

The Preliminary Draft Declaration was finalized by the IBC on January 2005. Responsibility for the passage of the text was then transferred from the IBC to the Intergovernmental Meeting of Experts. These experts represented

UNESCO Member States and met in April and June of 2005. The first meeting established a Drafting Group and elected a Bureau responsible for steering negotiations and finalizing the text prior to its adoption by the General Conference of UNESCO.

INITIAL FORM OF THE ARTICLE

At the first meeting of the IBC Drafting Group in April 2004, a draft outline of the structure of the Declaration was proposed:

Aims and scope

To ensure the application of science for the welfare of human beings and the development of humanity;

- The Declaration should underline the positive aspects of science and technology progress;
- The scope should be oriented towards the human being.

Following the release of this initial outline, the IBC Drafting Group agreed to define separately the Declaration's field of application (the 'Scope'), as distinct from the goals targeted in the principles set forth in the Declaration (the 'Aims') (IBC Drafting Group, 2004a). This structure was maintained in all subsequent drafts and the final text.

EVOLUTION OF THE TEXT

The first official draft prepared by the IBC Drafting Group, dated 15 June 2004, defined the scope of the Declaration as follows.

Scope

Bioethics, humanity [humankind / human beings] and the biosphere

This Declaration states the principles of bioethics primarily affecting [related to] human beings, while recognizing that human beings, as an integral part of the biosphere, have responsibilities and duties towards all other forms of life.

Human dignity, human rights and fundamental freedoms

The principles set out in this Declaration are founded on [are drawn from/ flow from] the respect for human dignity and the protection of human rights and fundamental freedoms [in accordance with international human rights law].

Consensus, diversity and pluralism

a. This Declaration affirms [states] that, through the universal principles set out therein based on shared values, common positions [decisions/solutions] in the field of bioethics should be reached for the benefit of humanity as a whole.
b. This Declaration acknowledges that ethical issues raised by scientific and technological development are set [reflected] in the cultural, philosophical and religious bedrock of the various human communities and that in some cases they should be addressed in the spirit of cultural pluralism inherent in bioethics.

It was evident from the outset that Article 1 would emphasize '*the human being*' as the primary subject of the Declaration's application. Although this focus would remain in the final text, it was not until the later stages of the drafting process that the scope was refined to be two-fold. That is, the Declaration was expressed as being 'addressed' to 'States', but 'applicable' to 'human beings'.

The text of Article 1 was substantially revised in the second draft, dated 27 July 2004. This draft reflected the desire of the IBC Drafting Group's to condense the text and remove unnecessary repetition in other provisions relating to 'General Principles' (IBC Drafting Group, 2004b). Thus, the second draft read:

Scope

The principles set out in this Declaration:

i. apply to human beings, while recognizing that human beings have responsibilities and duties towards other forms of life in the biosphere, and
ii. apply to issues raised by scientific and technological developments and their applications, as well as their availability and access.

This text remained unchanged in the third draft, dated 27 August 2004. Between October and December 2004, the IBC Drafting Group engaged in a period of extensive consultation, both written and oral, with key stakeholders, including Member States of UNESCO, NGOs and intergovernmental experts. Following these consultations, a revised draft was released, dated 15 December 2004:

Scope

a. The principles set out in this Declaration:
   (i) apply, as appropriate, to individuals, families, groups, communities as well as to public and private institutions, corporations and States and humankind as a whole;
   (ii) apply to bioethical issues;
   (iii) apply to any related decision or practice.
b. The principles set out in this Declaration apply to human beings, while recognizing that they have responsibilities towards other forms of life in the biosphere.

Despite this progress, the text again changed considerably prior to the release of the Preliminary Draft Declaration on 9 February 2005. These changes reflected the intensity of debate amongst the IBC Drafting Group and the IBC generally on the precise application of the Declaration. The amendments followed a joint session of the IBC and the IGBC, as well as an extraordinary session of the IBC, both held in late January 2005. For the first time, the provision included an express demarcation between 'decision-makers' in the fields of bioethics, and those to whom the decisions applied:

Scope

The principles set out in this Declaration apply as appropriate and relevant:

i. to decisions or practices made or carried out in the application of medicine, life and social sciences to individuals, families, groups and communities; and
ii. to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States.

However, because of the many changes to the text, debate over the wording of Article 1 was far from resolved. The Report of the First Intergovernmental Meeting of Experts, dated 6 April 2005, aimed at finalizing the text of the Declaration. It stated that the text would require further revision 'taking account of the debates being held on the field of application of the Declaration' (Report expert meeting, 2005). Indeed, the genesis of the final form of Article 1 appears evident from the following passage contained within that report:

> Some delegates also insisted that [Article 1] clearly state to whom the Declaration is addressed, making a distinction between the States and

> the other actors concerned, in accordance with the discussions held on the recipients of the text (Report expert meeting, 2005).

It was in response to this debate that the Chairperson of the Intergovernmental Meeting of Experts, Mr Pablo Sader (Uruguay), prepared a document to be considered by delegates in advance of the Second Intergovernmental Meeting of Experts in June 2005. His summation of the key points of division, together with suggestions as to how these could be resolved, was particularly insightful:

> *Use of terms and scope (articles 1 and 2)*
>
> The fundamental underlying conceptual divergence seems to be the extent of the notion of bioethics as applied to this Declaration. There are two schools of thought: a broader one that locates bioethics in its social and environmental context, and another one that restricts the concept to the ethical issues arising from medicine and life sciences.
>
> This basic divergence permeates the entire text of the draft declaration but it should not be irresolvable. The Chair hopes that it could be dealt with in the use of terms and scope articles, therefore facilitating the negotiation of the remaining articles.
>
> *In that spirit:*
>
> a. Would it be acceptable not to have a definition of bioethics as presently contained in article 1?
> b. Would the merger of articles 1 and 2 be acceptable?
> c. Would the concept of description rather than definition be acceptable?
> d. If the answer to the three previous questions is yes: Can we focus in the new article on what and to whom the Declaration applies?
> e. If so, and in reference to whom it applies, the Chair believes that some formulations based on the States as primary objectives of the Declaration and other actors as secondary recipients in a more residual capacity as appropriate, could be a possible compromise.
> f. As to the 'what': As bioethics does not evolve in a vacuum, can we include a contextual reference to social issues and the biosphere there?
> g. Would it be possible to drop definitions of 'decisions and practices' at this stage and come back to using these terms on a case-by-case basis, when they are applicable in other parts of the draft declaration?

The ensuing discussion of these questions informed the final text of Article 1 adopted in October 2005.

COMMENT ON THE HISTORY OF THE TEXT

The text of Article 1, as adopted in October 2005, is different from the text proposed in January 2005 by the IBC.

As finally recommended by the IBC, the Draft Declaration included a definition of 'bioethics'. It also included a definition of 'decision' and 'practice', that being the language in which each of the 'principles' of the Draft Declaration was then expressed. The IBC Drafting Group, and eventually the IBC, accepted that language in the expressed hope of rendering the principles of the Declaration more concrete, such that they would be enlivened in each case by 'decisions' and 'practices' of bioethical relevance, wherever arising. In meetings of intergovernmental experts, designed to ensure the acceptability of the proposed declaration to the Member States of UNESCO, in advance of its consideration at the General Conference, the repeated reference to 'decision' and 'practice' throughout the Principles was deleted. In harmony with the belief of many Member States that the 'Principles' should be expressed in more general terms and avoid the use of mandatory verbs ('shall', 'must'), the 'Principles' were restated as they now appear. Mandatory verbs were replaced by verbs thought more appropriate to the non-binding nature of the Declaration. Thus, 'should' and 'is/are to be' were substituted. The mandatory expression 'shall' was retained only in Articles 25.1 and 25.2 of the Declaration.

The consequence of this radical change to the IBC draft was to alter the format of the expression of the principles throughout the Declaration. It removed the perceived need for a definition of 'bioethics' and of decisions or practices within the scope of the Declaration. Reference to the scope and to 'decisions or practices' was retained in the opening words of the section of the Declaration on Principles. As adopted, this reads:

> Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected.

By these changes, the general provisions of the Declaration on scope were also altered. Nevertheless, because of the substituted opening words of the statement of the Principles of the Declaration, identification of its scope is important; hence, the significance of Article 1.

INTERPRETATION OF THE TEXT

The Declaration is not a treaty open to subscription and ratification by nation states or international organizations. It is not, therefore, as such, rendered part of international law by its adoption by the General Conference of UNESCO. As a matter of international law, such adoption does not bind the Member States legally to conform to the provisions of the Declaration. To the extent that the Member States assume some obligations and responsibilities under the Declaration, these are expressed in terms of the language of its provisions and, in particular, the terms of Articles 22, 23 and 24 concerning the role of States, their participation in bioethics education, training and information sharing and their encouragement of international co-operation in this respect. Articles 22, 23 and 24 are expressed by reference to the non-mandatory verb 'should'. Additionally, the Principles themselves, also being expressed in non-mandatory language, make clear the content of the State responsibilities assumed by participation in the decision of the General Conference to adopt the Declaration. The Declaration is hortatory, aspirational and educational rather than legally normative.

Nonetheless, in giving meaning to the provisions of the Declaration, it may be assumed that its provisions would be interpreted in a manner analogous to the way in which treaties are interpreted in international law. It is therefore useful to have regard, by analogy, to the Vienna Convention on the Law of Treaties ('The Vienna Convention'), Article 31 of which contains general rules of interpretation. Those rules substantially collect and express the proceeding principles of customary international law. The primary rule (Article 31.1 of the Vienna Convention) is that such instruments are to be 'interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the Treaty in their context and in the light of its object and purpose'. The reference to the 'purpose' permits regard to be had (Article 31.2) to a preamble and to admissible *travaux preparatoires*. The context is also to be taken into account, including any subsequent agreement regarding interpretation; any subsequent practice which establishes agreement about interpretation; and any relevant rules of international law (Article 31.3).

Different approaches to interpretation of texts in municipal and international law have coalesced in recent times in many legal systems towards a 'purposive' construction of written language, taking into account its purpose and context. The interpretation gives primacy to the written text. However, context, object and purpose are also considered in producing a 'holistic' interpretation of its language. At least in common law countries, this has

produced a more liberal approach to interpretation than was typical in the previous approach of municipal courts to discerning the meaning of domestic legal texts, which tended to be read more narrowly or literally. Recent shifts in many common law countries away from strict literalism and towards purposive construction have reduced the previous distinctions between the approaches to interpretation adopted in municipal and international jurisdiction (Diplock, 1978; House of Lords, 1981; High Court of Australia, 1998).

This being said, differences remain. Because international instruments are often drafted in multiple languages, involve input from experts of differing legal traditions and cultures and reflect many compromises and trade-offs in the process of negotiation, international texts, such as the Declaration, still require a generous approach to interpretation in order to ensure that they put into effect the imputed intention of those who adopted them. It may be inferred that this is especially so where the text expresses not a binding treaty but principles or guidelines designed to promote identified objectives and to point the various readers in directions considered desirable.

Nowhere is the need for a broad and liberal approach to construction more necessary than in general provisions of a non-binding international Declaration that express the ambit, purpose and intended operation of the Principles thereafter appearing. This is why it is customary and useful to have regard in the ascertainment of the imputed purpose, to such background materials as the *travaux preparatoires* contained in the record of the debates leading to the adoption of the Declaration. Such sources, whilst helpful, should not distract attention from 'the primary source of … interpretation' (Golder vs. United Kingdom, 1975). This remains a textual analysis. In the event of a conflict between the text and the apparent intention, purposes or wishes of the drafters, the duty of the interpreter is ultimately to the text, read as a whole and in the context of other relevant laws and principles. Against this background the following remarks may be made on the text of Article 1 of the Declaration (Scope).

TEXTUAL ANALYSIS

Article 1.1

'This Declaration': This phrase is a reference to the Universal Declaration on Bioethics and Human Rights, adopted by the General Conference of UNESCO in October 2005.

'Addresses': This is a word connoting the use of formal writing directed to identified persons or issues. The use of the verb 'addresses' in Article 1.1

is to be contrasted to the form appearing in Article 1.2 ('is addressed to'). No significance appears in the different language chosen in the two sub-articles. The words used in each sub-article express a factual feature of the Declaration. However, because the scope can, by the preambular words in the statement of principles, affect the application of the principles to particular decisions of practices, the factual statement takes on a normative flavour.

'Ethical issues': This expression is not defined in the Declaration. The IBC draft of the Declaration included a definition of 'bioethics' as:

> The systematic, pluralistic and inter-disciplinary study and resolution of ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications.

The deletion of 'social' sciences appears to be deliberate and designed to limit the scope of the ethical issues addressed by the Declaration. In this context 'ethical' means pertaining to, or dealing with, right and wrong in conduct, ordinarily in accordance with rules or standards for judging what is right or wrong conduct or practice. Note also that the language of Article 1.1 deletes reference to the relationship of human beings with the biosphere and to the availability and accessibility of scientific and technological developments and their applications. The reference to the biosphere elsewhere in the Declaration as adopted (notably in the provisions of Article 17) means that, by this express provision, the Declaration addresses issues of the biosphere as there specifically provided. However, the deletion of the reference from the terms of Article 1.1 in the statement of the scope of the Declaration has the effect that other principles, apart from Article 17, need not be interpreted, without a clear warrant in the text, as applying to the role of human beings in the protection of the biosphere.

'Related to': These words are generally taken as words of the widest connection. Similarly, 'issues' is a word of wide connotation. Accordingly 'issues related to medicine, life sciences and associated technology' is a very broad expression, apt to a definition of the scope of a declaration. The provision is designed to confine the 'ethical issues' subject to the Declaration to those identified. Thus, ethical issues related to philosophy, law and the social sciences, as such, are not included in the scope of the Declaration unless, in the particular case, they are 'related to' the disciplines and developments mentioned in Article 1.1. The word 'medicine' would usually connote therapeutic and

other means addressed to the benefit of human beings and other higher forms of life. The phrase 'life sciences', on the other hand, has a more general focus. It denotes the sciences that study living matter in all of its variety, including where it manifests itself in primitive and rudimentary forms. However, the width of this focus is potentially cut back by the reference to application 'to human beings'.

'As applied to human beings': The text is not clear whether this phrase qualifies 'associated technologies' or the entire preceding expression 'medicine, life sciences and associated technologies'. Given the context, it appears likely that the drafters intended the necessity of application to human beings as a requirement for each of the ethical issues in Article 1.1. To this extent, the text incorporates an anthropomorphic view of the scope of the Declaration.

'Taking into account their social, legal and environmental dimensions': This phrase appears to be a corrective against any narrow view of the words 'human beings'. In short, the application to 'human beings' is not confined to medical aspects of human life presenting ethical issues. In the past, this has often been the traditional area of bioethical discourse. It has been one substantially dominated by the health care professions. The inclusion of the social, legal and environmental dimensions of human beings broadens this more traditional focus of bioethics. Specifically, the reference to 'legal … dimensions' incorporates reference to international law, specifically international human rights law. Whilst some traditional commentators, yearning for the maintenance of a medical model of bioethics, have criticized the perceived confusion of law and ethics that permeates the document (Jing-Bao, 2005; Williams, 2005; Wolinsky, 2006), the adoption in the scope of the Declaration of an approach that combines the previous medical and scientific concerns about bioethics with the principles of international human rights law, is a deliberate one (Andorno, 2007). It was a major objective of the IBC and its Drafting Group.

Article 1.2

'*This Declaration*': This is a reference to the Universal Declaration on Bioethics and Human Rights, adopted by UNESCO in October 2005.

'*Is addressed to States*': This expression makes it clear that the primary addressees of the Declaration are the nation states that are members of the international community, specifically of UNESCO, whose declaration this is. One object of the previous manner of drafting the Principles

contained in the IBC Draft was to afford a statement of principles that would influence 'any decision or practice' having bioethical application or relevance. Understandably, the intergovernmental meeting of experts, representing Member States of UNESCO, emphasized the purpose of the instrument as being to address States, as such, and to recommend a role for them in giving effect to the Principles (Article 22); in fostering relevant education, training and the exchange of information (Article 23); and in promoting international co-operation in scientific and technological knowledge (Article 24).

'*As appropriate and relevant*': In the ensuing elaboration of the obvious fact that the Declaration provides guidance for the decisions and practices of recipients other than States, the Declaration omits a precise identification of the ambit and occasions in which such guidance will be given beyond that specifically addressed to States. No detail or elaboration is afforded of when it will be 'appropriate and relevant' to read the Declaration as providing guidance beyond nation states. One view would be that it is for the States themselves to so decide, by the adoption of their own municipal laws and policies. Another view, which seems the preferable one, is that it is left within the States to the natural and legal persons identified to decide to what extent the Principles in the Declaration are 'appropriate and relevant' for their 'decisions or practices'.

Given that the Declaration purports to state general principles in language that is not mandatory in its expression, the reference to 'natural and legal persons' and the use that they may make of the Declaration simply recognizes, as is stated, that the Principles are to be respected in decisions or practices taken or carried out 'by those to whom it is addressed'. This leaves the addressee of the Declaration to be identified from the language of the particular principles or from other contextual considerations.

'*Provides guidance to decisions or practices*': The reference to 'decisions or practices' was formerly a repeated operative phrase in the IBC Draft of the Declaration. Although it has been removed as a common expression in the statement of each of the principles, the reference is retained in Article 1.2 and in the preambular words before the statement of the principles in Articles 3–17. The reference to 'decisions' is a reference to individual choices made in the particular instances or circumstances to which the Declaration is addressed, and in particular in the Principles themselves. The reference to 'practices' is a reference to standards of conduct and regular modes of addressing 'decisions' of the kind described.

'*Of individuals, groups, communities, institutions and corporations, public and private*': The range of natural and legal persons brought within the scope of the Declaration is extremely wide. It includes natural persons ('individuals') and legal persons ('groups, communities, institutions and corporations'). Note that elsewhere in the Declaration collective expressions appear which are not exactly the same as the collection in Article 1.2. Thus in the twelfth paragraph of the Preamble, reference is made to the benefits of science and the promotion of the welfare of 'individuals, families, groups or communities and humankind as a whole'. In the fourteenth paragraph of the Preamble, reference is made to the impact of decisions on ethical issues 'on individuals, families, groups or communities and humankind as a whole'. This collection of interested subjects is not repeated in the substantive paragraphs of the Principles. See Article 1.2, 2(b) and compare the specific focus mentioned in the Principles stated in Article 11 ('no individual or group'); Article 14.2(a) ('women and children'); Article 16 ('future generations') and Article 17 ('human beings … the environment, the biosphere and biodiversity').

'*Application of the provisions*': The provisions of Article 1 identify the intended scope of the Declaration. However, as is plain from Article 1.2, it is largely left to the nation states which adopted the Declaration at the General Conference of UNESCO, acting through their ordinary procedures of law and policy-making, to decide the extent to which effect will be given to the Declaration and its Principles. Similarly, it is left to individuals and the nominated groups within the nation State to decide the extent to which (if at all) they will, in their 'decisions or practices' accept and implement the Principles in the Guidelines as affording guidance to themselves. States have no legal duty to implement the Guidelines. This is made clear by the use of the non-mandatory expression 'should take all appropriate measures' in Article 22.1. Nevertheless, because the Declaration was adopted unanimously by the General Conference of UNESCO, without any State recording its dissent, reservation or qualification, it may be assumed that the participating States accepted the Declaration, as they did, in good faith and with the intention of following up its provisions in such ways, and at such time, as seems suitable to them. Because of the non-mandatory language in which the Principles themselves are stated ('should'), ('is/are to be'), ('is') and ('may'), the carrying into effect of the Principles, whether at the State level or at the level of decisions and practices of natural or legal persons, is left to the State and to the individuals or legal persons concerned.

'*Illustrations*': The scope of the Declaration is important for all that follows. In particular instances, where the State or an individual or

legal person, are considering whether, for particular bioethical decisions, useful guidance is afforded by the Declaration, instances may arise where the Principles themselves are ambiguous because of the general language appearing in particular provisions.

In such instances, it may be useful for the decision-maker to have regard to the statement of the intended scope of the Declaration contained in Article 1. Thus, for example, the Declaration is not a general statement governing decisions of concern to the environment, the biosphere and biotechnology. On the other hand, such considerations are mentioned, notably in Article 17. To decide whether, in the particular case, the general principles of the Declaration apply to a matter affecting the biosphere or the environment, guidance can be derived from the provisions as to scope. These provisions make it clear that the primary focus of concern of the Declaration is generally upon the impact on ethical decision-making of medicine, life sciences and associated technologies as applied to human beings. Whilst that application is expanded by the reference to the 'social, legal and environmental dimensions' of human beings, the stated provision as to scope suggests that more general ethical questions concerning biodiversity, animal welfare and the environment will need to be addressed in further, more specific and detailed instruments that are more directly addressed to such concerns.

This said, the specific acknowledgment in Article 1.2 that 'as appropriate and relevant' the Declaration provides guidance to decisions or practices by natural and legal persons, beyond the State, signifies the wide potential operation of the Declaration. An objective of the IBC, in its formulation of the Principles, was to state general principles in a manner that would permit them to be identified, to stand alone, so that they could be available at the work desk, in the laboratory, for the boardroom and elsewhere where ethical questions presented by any aspect of biology arose to be decided. They would thus afford the decision-maker a checklist of principles. Whilst the formulation of the Principles has been changed by the intergovernmental experts, the broad focus adopted in Article 1.2 indicates that the General Conference of UNESCO preserved the overall intention of the IBC that the Declaration should have a broad operational and educative effect. It is not, as such, wholly dependent on initiatives of law or policy-making taken by Member States. It is addressed, by its terms, in language that may be utilized by relevant decision-makers, including individuals, and in families and groups and communities when faced with dilemmas of bioethical concern. To this extent, the Declaration as adopted carries forward the broad objective of the IBC and its Drafting Group.

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Chapter 4

ARTICLE 2: **AIMS**

Michael Kirby

Article 2 – Aims

The aims of this Declaration are:

a. *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;*
b. *to guide the actions of individuals, groups, communities, institutions and corporations, public and private;*
c. *to promote respect for human dignity and protect human rights by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;*
d. *to recognize the importance of freedom of scientific research and benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within a framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;*
e. *to foster multi-disciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;*
f. *to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;*
g. *to safeguard and promote the interests of the present and future generations;*
h. *to underline the importance of biodiversity and its conservation as a common concern of human kind.*

DRAFTING HISTORY

Whereas Article 1 underwent substantial change at several junctures in the drafting process of the Declaration, Article 2 remained ostensibly the same throughout.

There were six official drafts of the Declaration prepared by the IBC Drafting Group prior to the adoption of the final text by the 33rd session of the General Conference of UNESCO in October 2005. A brief chronology of these drafts as follows:

30 April 2004	Draft outline of the structure of the Declaration finalized by the IBC Drafting Group
15 June 2004	First draft finalized by the IBC Drafting Group
27 July 2004	Second draft finalized by the IBC Drafting Group
27 August 2004	Third draft finalized by the IBC Drafting Group
15 December 2004	Fourth draft finalized by the IBC Drafting Group
9 February 2005	Preliminary Draft Declaration finalized

INITIAL FORM OF THE ARTICLE

At the first meeting of the IBC Drafting Group in April 2004, a draft outline of the structure of the Declaration was formed. This First Outline grouped the aims and scope of the Declaration together as follows:

Aims and scope

- To ensure the application of science for the welfare of human beings and the development of humanity;
- The Declaration should underline the positive aspects of science and technology progress;
- The scope should be oriented towards the human being.

Following the release of this initial outline, the IBC Drafting Group agreed to separately define the Declaration's field of application (the 'Scope'), as distinct from the goals targeted in the principles set forth in the Declaration (the 'Aims') (IBC Drafting Group, 2004a). This structure was maintained in all subsequent drafts and the final text.

EVOLUTION OF THE TEXT

The first official draft, which followed the initial draft outline of the structure of the Declaration, listed the aims as follows:

- to promote respect for life in all its diversity and in particular [including] respect for human life;
- to ensure the respect for human dignity and the protection of human rights and fundamental freedoms in [the sphere of] bioethical decision making, in accordance international human rights law;

- to recognize an understanding of the great benefit derived from scientific and technological development, whilst ensuring that such development occurs within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms;
- to provide a universal framework of fundamental values, [core principles] and basic procedures designed to guide States in the formulation of their legislation and their policies in the field of bioethics, and to form the basis for guidelines in bioethical matters for the institutions, groups and individuals concerned;
- to foster dialogue between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual and professional groups concerned, policy-makers and society as a whole;
- to prevent practices contrary to human dignity such as those that undermine the respect for individuals and for the diversity of humankind;
- to promote the sharing and the greatest possible flow of knowledge concerning the scientific and technological development as well as the sharing of benefits, in particular with developing countries;
- to safeguard the interests of present and future generations.

Following further meetings of the IBC Drafting Group, it was decided to re-order the aims. Although the aims were not necessarily hierarchical, there was common agreement that the primary aim of the Declaration was to provide a 'universal framework of principles and procedures ...'. It was also decided to remove the direct reference to 'human life' given the general reference to 'human rights'. The other aims were also condensed, with an additional aim added in relation to biodiversity (IBC Drafting Group, 2004b). These changes were reflected in the second draft, dated 27 July 2004:

Aims

The aims of this Declaration are:

- to provide a universal framework of fundamental principles and basic procedures designed to guide States in the formulation of their legislation and their policies in the field of bioethics, and to form the basis for guidelines in bioethical matters for the institutions, groups and individuals concerned;

- to ensure the respect for human dignity and the protection of human rights and fundamental freedoms in [the sphere of] bioethical decision making, in accordance with human rights law;
- to promote respect for biodiversity;
- to recognize the great benefit derived from scientific and technological developments, whilst ensuring that such development occurs within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms, and to prevent practices contrary to human dignity;
- to foster dialogue between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual and professional groups concerned, policy-makers and society as a whole;
- to promote the sharing and the greatest possible flow of knowledge concerning scientific and technological developments as well as the sharing of benefits, in particular with developing countries;
- to safeguard the interests of present and future generations.

Aside from minor alterations to the structure and wording of the aims, the text of Article 2 remained virtually unchanged. Following the consultation with key stakeholders between October and December 2004, an additional aim promoting 'equality in scientific developments' was included. However, this was subsumed within the aim concerning the 'sharing of scientific and technological developments' in the Preliminary Draft Declaration. In that draft, although the list of aims remained virtually identical to earlier drafts in terms of substance, the language used had been modified and extended:

> The aims of this Declaration are:
>
> i. to provide a universal framework of fundamental principles and procedures to guide States in the formulation of their legislation and policies in the field of bioethics, and to form the basis for guidelines concerning bioethical issues for the individuals, groups and institutions concerned;
> ii. to promote respect for human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law;
> iii. to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological

developments, whilst ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms;

iv. to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious and professional groups concerned, olicy makers, non-governmental organizations, representatives of civil society, the persons concerned and society as a whole;

v. to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;

vi. to recognize the importance of biodiversity and the responsibilities of human beings towards other forms of life in the biosphere; and

vii. to safeguard and promote the interests of the present and future generations.

Following the release of this draft, the content of the Aims provision was virtually settled. However, given the debate surrounding the scope and application of the Declaration, it was decided to include sub-paragraph (b) to encompass the impact of the Declaration on decisions or actions that are not made by States directly. The wording of the Article was also considerably tightened.

INTERPRETIVE PRINCIPLES

The statement of the aims of the Declaration, appearing in the General Provisions, is relevant to the interpretive principles which, by analogy, are available for the interpretation of a non-binding declaration such as this. Because the Declaration is expressed in general language, and is sometimes ambiguous representing the compromises reached in its drafting, a statement of the aims is useful as affording guidance of the purposes of the Declaration as accepted by the nation states that accepted it in the General Conference of UNESCO.

The Declaration is not a treaty and, for this reason, the principles of international law governing the interpretation of treaties do not apply to it. However, those principles, including as stated in the Vienna Convention on the Law of Treaties, are available to decision-makers, by analogy, to the

extent that they are relevant and applicable, to extract the meaning of the Declaration. The starting point is the text. However, the context and purpose of the Declaration, read as a whole, is an important source of the meaning of any contested language. Ultimately, the text of the Declaration governs the meaning that is to be derived from it. Nevertheless, the elucidation of meaning may be assisted by the reaffirmation of important aims and by the ways in which those aims are expressed. A purposive and liberal interpretation of an instrument such as the Declaration is appropriate, not least because of the permissive and non-mandatory language in which its substantial terms are stated.

COMMENT ON THE HISTORY OF THE TEXT

The statement of the aims of the Declaration, as expressed in the Draft recommended by the IBC, was modified by the Intergovernmental Meeting of Experts. To some extent, the alteration of the principles stated in the Declaration necessitated an alteration of the list of aims. Generally speaking, the aims, after specifying those which are of relevance for the guidance of States, the first addressees of the Declaration (see Article 1.2) and natural and legal persons, the second addressees (see Articles 1.2 and 2(b)) generally follow the structure of the Principles. Thus, the aim stated in Article 2(c) ('promotion of human dignity and protection of human rights') encompasses the more detailed principles expressed, in substantive terms, in Articles 3, 4, 5, 6, 7, 8, 9, 10 and 11. The aim in Article 2(d) (benefits of scientific research) is reflected in the substantive terms of Articles 14 and 15. The fostering of the provisions of Article 2(e) for fostering dialogue between 'all stakeholders and within society' is reflected in Article 13 (solidarity and co-operation) and Article 15 (sharing of benefits). The terms of Article 2(f) is reflected in Article 14 (social responsibility and health) and Article 15 (sharing of benefits). The provisions of Article 2(g) (present and future generations) is exactly reflected in substantive terms in Article 16 (protecting future generations). Similarly the aim expressed in Article 2(h) (biodiversity) is reflected in Article 17 (protection of the environment, the biosphere and biodiversity).

A question arises as to what the statement of the aims adds to what would otherwise be the derivation of the aims from the substantive terms of the Principles collected in the immediately following section of the Declaration. To the extent that an aim is more narrowly expressed, does it in any way detract from, or reduce the ambit of, the substantive principle? Thus, for example, the aim stated in Article 2(h) ('to underline the importance

of biodiversity and its conservation as a common concern of humankind') is narrower in focus and scope than the substantive principle expressed in Article 17. The latter is targeted with the interconnection of human beings with other forms of life. It adds reference to the importance of access to, and utilization of, biological and genetic resources. It supplements this reference with one to 'respect for traditional knowledge'. The focus of its provisions extends to the environment and the biosphere and not just to 'biodiversity' and its conservation. What, then, is the added value of the statement of the aim in Article 2(h)?

The apparent answer to this question is to be found in the verb expressing the object of the aim in Article 2(h): 'to *underline* the importance' of biodiversity. It thus appears amongst the objectives expressed in the substantive principle in Article 17. But, by reference to the aim in Article 2(h) that importance is 'underlined'. By underlining it, it may be inferred that the States that endorsed the Declaration wish to give priority of attention and importance to biodiversity and its conservation. This is an understandable objective of UNESCO given its programme including Man in the Biosphere (MAB).

To the extent that the Principles expressed with more specificity the approaches and guidelines that should be adopted, as appropriate and relevant, in guiding decisions or practices in accordance with Article 1.2, these govern the substantive rules. The statement of the aims cannot detract from the Principles so stated. On the other hand, such a statement can give particular emphasis, urgency and priority to the substantive provisions expressed in the principle to which the aims closely relate. Sometimes, the elaborate and particular aims improve the content of the general provision as to the scope of the Declaration (Article 1) or the more particular provisions containing the Principles and the promotion of the Declaration.

An illustration is the aim in Article 2(a). In Article 1.2, it is simply stated that the 'Declaration is addressed to States'. What States should do is then expressed in non-mandatory terms in Articles 22, 23 and 24. But the way in which States should act in accordance with those Articles is not spelt out except in the aim expressed in Article 2(a). This makes it clear that the purpose of the Declaration is to provide a universal framework of principles and procedures to guide the States. Moreover, it is to do so in 'the formulation of their legislation, policies or other instruments'. This phrase signals the descending hierarchy of normative provisions that might be adopted by a State in furthering the Principles of the Declaration. That hierarchy could extend from legislation (binding law) through policies (official rules or guidelines,

possibly adopted within binding law) and 'other instruments' (including non-binding statements and delegated legislation). Given the variety and significance of norms in the field of bioethics, depending for their importance and urgency on many factors, this range of State responses is unsurprising.

Whereas the aim in Article 2(a) refers to the first sentence in Article 1.2, the aim in Article 2(b) reflects the same language as appears in the second sentence ('individuals, groups, communities, institutions and corporations').

The reference in Article 2(c) to promotion of respect for 'human dignity' is sometimes regarded as controversial, although the phrase is repeated in Article 3.1 and reflected in the language of Article 11. Some commentators suggest that the ultimate foundation of human rights is respect for human dignity, inhering in each individual. Others express concern that the notion of 'human dignity' is ambiguous; cannot be used to derogate from binding statements of international law founded in the decisions of the international community; and sometimes suggests theist or religious foundations for human rights that are not universally accepted.

The reference in the aim in Article 2(c) to 'human dignity' and to the need to ensure 'respect for the life of human beings' is itself ambiguous; it was, in fact, added by the intergovernmental experts. Some readers will draw the inference that, by adopting the aim in paragraph (c) of Article 2, UNESCO has endorsed notions of right to life that are strongly held by some countries and by certain religious groups. However, paragraph (c) must be read against the background of earlier work of the IBC concerned with the controversies surrounding the beginning of human life. This research was performed in connection with consideration of the controversial issue of the use of embryonic stem cells. Different religions adopt quite different conclusions as to when 'the life of human beings' begins, that is whether at conception, at some later stage *in utero,* or at birth. The statement of the aims in Article 2(c) does not alter the substantive principles contained in the Declaration. Nor does it resolve the ambiguities and debates that revolve around this question.

The provisions of Article 2(d) reflect the way in which, elsewhere in the Declaration, an internal tension appears in a provision. Thus, this aim recognizes the importance and benefits of scientific and technological developments. But it also stresses the need for these to occur in a framework of ethical principles that include respect for human dignity, human rights and fundamental freedoms. A similar balance exists in Article 12 ('respect for cultural diversity and pluralism'). In its primary provision, Article 12

calls for 'due regard' to be given to the 'importance of cultural diversity and pluralism'. But it affirms that such considerations are not to be invoked 'to infringe upon human dignity, human rights and fundamental freedoms'. Nor are they to limit the Principles contained in the Declaration or the scope of its application. The latter provisions reflect in a general way the terms of the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, mentioned in paragraph six of the Preamble to the Declaration.

Put generally, the statement of aims in the Declaration clarifies the purpose so far as States are concerned of providing a 'universal framework of principles and procedures'. It reinforces the objectives, inferred from the provision of Article 1.2 on 'Scope', that the Declaration should guide natural and legal persons. It affords specific aims relevant to the principles that immediately ensue. It gives emphasis to some features of those principles whilst not qualifying their general application as expressed in their own language. In the event of ambiguity in the terms of the principles stated in the Declaration, the reader must consider the general provisions as to scope and the statement of the aims, in the hope that these may combine to resolve the ambiguity or point the decision-maker in the right direction.

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Chapter 5

ARTICLE 3: **HUMAN DIGNITY AND HUMAN RIGHTS**

Roberto Andorno

Article 3 – Human dignity and human rights

1. *Human dignity, human rights and fundamental freedoms are to be fully respected.*
2. *The interests and welfare of the individual should have priority over the sole interest of science or society.*

WHY DOES THIS ARTICLE APPEAR IN THE DECLARATION?

The principle of respect for human dignity holds a prominent position in the intergovernmental instruments dealing with biomedicine that have been adopted since the end of the 1990s, such as the Universal Declaration on the Human Genome and Human Rights of UNESCO (11 November 1997) and the Convention on Human Rights and Biomedicine of the Council of Europe signed on 4 April 1997. It is therefore not surprising that the Universal Declaration on Bioethics and Human Rights, that formulates a set of norms for guiding biomedical practices, assigns first place to the principle of 'human dignity, human rights and fundamental freedoms' (Article 3, line 1).

The requirement of respect for human dignity, which has been characterized as the 'cardinal principle of the legal norms relating to bioethics' (Lenoir and Mathieu, 1998: 15), is certainly not new in international law. Beginning with the Universal Declaration of Human Rights (1948), which affirms that 'recognition of the inherent dignity (…) of all members of the human family is the foundation of freedom, justice and peace in the world', this principle has been at the heart of most international human rights instruments, especially those banning torture, slavery, inhuman and degrading treatments and discriminations of all sorts.

However although this principle has always held an important position in international law, the key role it plays in the emerging international biomedical

law is absolutely unique. The Explanatory Memorandum of the Preliminary Draft Declaration on Universal Norms on Bioethics leaves no doubt on the significance of this notion when it cites as 'an important achievement' the fact that 'it anchors the principles that it espouses firmly in the rules governing human dignity, human rights and fundamental freedoms' (UNESCO, 2005: para. 12). It should be noted that the promotion of the respect for human dignity forms part of the aims of the Declaration (Article 2(c)). In addition, human dignity is explicitly invoked as an argument against discrimination (Article 11), as well as the framework within which cultural diversity is to be respected (Article 12), and as an interpretative criterion of all the provisions of the Declaration (Article 28). Likewise, it is interesting to note that the need to include the principle of respect for human dignity was one of the points most often mentioned by Member States during the preparatory consultations that took place between January and March 2004 (IBC, 2004: para. 10; some issues concerning the evolution of this article are also discussed by Pellegrino in the next chapter in this volume).

What are the reasons for this striking insistence on human dignity that can be found in international instruments relating to bioethics? The answer is very simple: biomedical practices are closely related to basic prerogatives of every human being, namely the right to life and to physical and mental integrity. If human dignity is generally recognized as the foundation on which human rights are based, then it is normal that it is mentioned as the ultimate rationale of legal frameworks for regulating biomedical activities. But there is another reason explaining this phenomenon. The notion of human dignity is beginning to be considered as the last barrier against the alteration of some basic characteristics of the human species that might result from practices such as reproductive cloning or germline interventions. It should be noted that resorting to human rights is insufficient to cope with these new challenges because human rights only apply to existing individuals or groups of individuals, not to humanity as such (Zanghi, 1998). However, the above-mentioned practices go beyond individuals, risking harming humankind as a whole, including future generations. This is the reason why the Universal Declaration on Human Genome and Human Rights directly appeals to the notion of human dignity to reject both practices (Articles 11 and 24).

Article 3.2 stipulates that 'the interests and welfare of the individual should have priority over the sole interest of science or society'. This basic principle was outlined for the first time in 1964 in the famous Declaration of Helsinki for medical research on human subjects developed by the World Medical Association. Thereafter, it was incorporated into the Universal

Declaration on the Human Genome and Human Rights (Article 10) and into the Convention of Human Rights and Biomedicine of the Council of Europe (Article 2). The primacy of the human being over science is a direct corollary of the principle of respect for human dignity and aims to emphasize two fundamental ideas: First, that science is not an end in itself but only a means for improving the welfare of individuals and society; second, that people should not be reduced to mere instruments for the benefit of science. Certainly, the fact of living in society renders it indispensable that citizens should in some way contribute to the common good, according to their capacities and preferences. However, in democratic societies, people do not live for the sake of society or technology, but have their own purpose, which greatly transcends the boundaries of social or scientific interests.

WHAT IS THE MEANING OF THE ARTICLE?

The notion of human dignity is very frequently used by international human rights instruments, but is never defined. The Universal Declaration on Bioethics and Human Rights is not an exception in this regard. It is only at the level of the Explanatory Memorandum of the Preliminary Draft Declaration, which does not have normative value, that some explanation of the meaning of this notion is provided (UNESCO, 2005: para. 40). This lack of definition has brought some bioethicists to argue that dignity is a simple slogan without any practical relevance. It would merely be synonymous with 'respect for autonomy' of patients and research subjects. Hence it could simply be abandoned without any loss (Macklin, 2003).

This last conclusion seems unjustified. Certainly it is not easy to define the expression 'human dignity' in clear and unambiguous terms. But the same happens with all basic moral concepts (justice, freedom, love, etc.) and nobody argues that we should abandon all these fundamental notions. It is also true that the bioethical debates show often an inflationary use of the term 'dignity' that should be avoided, especially when no additional explanation is given to make it clear why a particular practice is regarded as being in conformity (or not) with this principle. However, beyond all the abusive rhetoric surrounding this notion, the reality is that it reflects a real concern about the need to ensure respect for the inherent value of every human being and of humanity. This concern is by far broader than simply ensuring 'respect for autonomy', for the simple reason that it also includes the protection of those who are not yet, or who are no longer, morally autonomous (newborns, persons suffering from serious mental disorders, etc.). Because, in one way or another, the idea of

dignity has to do with the *spiritual* dimension of human existence and relates to the conviction that what makes us human cannot be found only at the biological or genetic level (Lenoir and Mathieu, 1998: 16).

In short, as 'human dignity' refers to the intrinsic value of every human being, it is by definition equal for all humans. It does not admit any degrees. It cannot be gained or lost. Such a notion embodies the idea that 'something is due to the human being because of the sole fact that he or she is human' (Ricœur, 1988: 236; De Koninck, 1995). This means, more concretely, that all human beings deserve utmost respect, regardless of their age, sex, health status, social or ethnic origin, political ideas or religion.

Such understanding of human dignity is implicit in most international human rights law instruments. This can be called the 'individual dimension' of dignity, which is the foundation of all rights and freedoms and leads to the need to promote self-determination and protect people against any inhuman or degrading treatment. However, there is another, more recent category of dignity that can be called 'collective' in the sense that it goes far beyond the mere individual sphere. It refers to the value of humanity *as a whole*, including future generations. The reasoning on which it is based is the following: If all human beings have inherent dignity and should be respected unconditionally, then the larger group they belong to (humanity) possesses also, *in a derivative way,* intrinsic value. This extended notion of dignity lies in the background of some provisions of the international instruments relating to bioethics, in particular those regarding some biotechnological developments that may affect the identity and integrity of humankind as such. It amounts to a sort of 'species solidarity' and inevitably leads to prescribe some limits on potential developments that could be harmful for the identity and integrity of humanity (Manaï, 2006: 20–22).

However, in our view, it would be inadequate to see both dimensions of dignity as if they were two rival notions (Beyleveld and Brownsword, 2002: 27–29; Caulfield and Brownsword, 2006). The two facets of human dignity are not really mutually exclusive but complementary, in the same way that 'rights' and 'duties', or freedom and responsibility, are complementary notions. Indeed, the same principle stating that human beings have intrinsic value results in two consequences. First, each individual is entitled to fundamental rights and freedoms (individual dimension of dignity), most of which are of course not absolute but subject to such reasonable limits as are justifiable in a free and democratic society. Second, in a derivative manner, humanity as such has inherent value and therefore its integrity and identity deserve to be protected from a misuse of biotechnological developments (collective dimension of dignity) (Birnbacher, 1996; Andorno, 2005).

To further understand the idea of dignity, it is helpful to refer to the famous Kantian formula stating that persons should always be treated as an end in themselves and never as a means only (Kant, 1911: 428). According to this view, dignity is exactly the opposite of 'price', that is the kind of value for which there can be equivalent, whereas 'dignity' makes a person irreplaceable. This understanding of dignity embodies a requirement of non-instrumentalization of persons, which is extremely illuminating in bioethics. It means, for instance, that no one should be submitted to biomedical research that put his or her life at serious risk or without his or her informed consent, even when very valuable knowledge could result from that research; that it is unacceptable that people in extreme poverty would be induced to sell their organs as a means to support themselves or other family members; that no one has the right to produce human clones or to predetermine the genetic traits of a child to satisfy the wishes of potential parents or supposedly in the interest of society. All these cases illustrate different forms of instrumentalization of the human person and therefore practices that are contrary to human dignity.

Beyond these extreme examples, the view of the human being as an end in itself plays a major role in everyday medical practice by stressing the uniqueness of every patient and of his or her particular needs. In this way, it greatly contributes to enhance the quality of the doctor-patient relationship, helping to keep alive the idea that each patient, no matter what his or her diagnosis, is not a 'case' or a 'disease', but a *person* with a unique character.

HOW CAN THE ARTICLE BE APPLIED?

Although international norms relating to bioethics attribute a central role to the respect for human dignity, it has to be recognized that this principle alone cannot solve most bioethical dilemmas. Dignity is not a magic word that can simply be invoked to find a precise solution to the complex challenges posed by medical and genetic advances. To become *functional,* dignity needs other more concrete notions like 'informed consent', 'physical integrity', 'confidentiality', 'non-discrimination', amongst others, which are normally formulated by using the terminology of 'rights'.

It is therefore not by chance that Article 3.1 of the Universal Declaration on Bioethics and Human Rights adds 'human rights and fundamental liberties' when referring to human dignity. In fact, the whole Declaration is conceived as an extension of international human rights law into the field of biomedicine. According to the Chairperson of the Drafting Group,

'the most important achievement of the text' consists precisely in having integrated the bioethical analysis into a human rights framework (Kirby, 2005: 126). As noted by the above-mentioned Explanatory Memorandum, 'the Drafting Group also stressed the importance of taking international human rights legislation as the essential framework and starting point for the development of bioethical principles' (UNESCO, 2005: para. 11). This document also points out that there are two broad streams at the origin of the norms dealing with bioethics. The first one can be traced to antiquity, in particular to Hippocrates, and is derived from reflections on the practice of medicine. The second one, conceptualized in more recent times, has drawn upon the developing international human rights law. Furthermore, it states: 'One of important achievements of the Declaration is that it seeks to unite these two streams. It clearly aims to establish the conformity of bioethics with international human rights law' (UNESCO, 2005: para. 12).

Another reason for the use of a human rights framework is that it facilitates the formulation of *universal standards*, because international human rights law is based on the assumption that some basic rights *transcend cultural diversity*. In such a sensitive field as bioethics, where socio-cultural, philosophical and religious traditions come into play, this key feature of the human rights framework should not be underestimated.

Finally, a third reason for resorting to human rights is that since the adoption of the Universal Declaration of Human Rights in 1948, a large number of international instruments have been adopted to ensure the unconditional respect for the human person in very diverse contexts. Furthermore, the existing human rights system, with its extensive body of international standards and wide range of follow-up mechanisms, represents one of the most remarkable achievements of our time. Therefore, it is normal to make use of this rich normative and institutional set-up in order to protect people from harm in the field of biomedicine. In this respect, as a well-known expert on public health issues pointed out, 'the human rights framework provides a more useful approach for analyzing and responding to modern public health challenges than any framework thus far available within the biomedical tradition' (Mann, 1996).

In sum, the recourse to human rights in order to render functional the principle of human dignity does not make the latter superfluous or purely rhetoric. In spite of its general nature, the idea of human dignity provides the necessary conceptual background for responding to the new concerns about respect for persons in clinical and research settings, and for humanity as a whole.

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Chapter 6

ARTICLE 4: **BENEFIT AND HARM**

Edmund D. Pellegrino

Article 4 – Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, 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.

INTRODUCTION

The Universal Declaration on Bioethics and Human Rights is a logical and timely extension of the principles of the Universal Declaration of Human Rights (1948), which has as its central principle the dignity and equality of all human persons. The UNESCO Declaration extends the rights set forth by the earlier UN Declaration to the emerging field of bioethics. The logical and the ethically grounded linkage is through the inherent dignity and equality of all human persons. Human dignity is the leitmotiv of both documents and the grounding for the moral and legal obligations that follow from both documents.

This contribution will discuss the implementation of Article 4 of the Universal Declaration as the application of the ethical principle of beneficence and non-maleficence. It begins with the way the principle of beneficence is grounded in human dignity; it proceeds then to the moral sanctions that permit risks to be run in medical therapy and research and the criteria for assessing risks and benefits if beneficence is to be optimally applied. The contribution closes with a definition of the central place of the character of the physician, physician investigator and other health professionals when conflicts of interest and obligations arise in the implementation of Article 4.

Given the close articulation and mutual re-enforcement of Article 4 with the other principles of the Declaration, this contribution will delimit itself to avoid overlap and repetition with other principles.

HUMAN DIGNITY AND THE PRINCIPLE OF BENEFICENCE

Article 4 of the Declaration follows logically and unequivocally from Article 3: 'Human dignity and human rights'. The subsequent principles (Articles 5–16) are corollaries and deductions from Article 1 and 2, particularly the aim of Article 2 'to promote respect for human dignity and protect human rights.'

All of this is congruent with the first principle of the Universal Declaration of Human Rights (1948). Thus the UNESCO Declaration and the UN Declaration of 1948 are parts of an integral whole, which grounds both rights and ethics in the inherent dignity and equality of human beings. The solidarity between and among humans discussed later in the Declaration, follows logically from the acceptance of the equality and dignity of individual human persons (IBC, 2004: 84–85).

Recognition of the central place of dignity in human rights and ethics takes into account the obligations of the human species for other living beings and for the biosphere as well. Only the human species has the capacity to act in such a way that it can responsibly do direct and intended good or harm to the biosphere. Hence only the human species can be responsible for its own welfare and that of the biosphere.

There was agreement on Article 3, in principle, *mutatis mutandis*, among a variety of religious representatives who commented on the draft statement. These representatives came from the Muslim, Confucian, Buddhist, Hindu, Roman Catholic and Hebrew religious traditions (UNESCO, 2004). Each emphasized somewhat different facets of the concept of human dignity. All, however, accepted human dignity as a valid grounding for both bioethics and human rights. Most agreed as well that humans had moral obligations to protect the other species in the biosphere. Thus, the ascription of dignity to humans implies respect by humans for other living beings in the biosphere, hence to accept stewardship for the care of the biosphere.

Additional comments were obtained from 27 Member States, four intergovernmental groups as well as representatives of 13 national bioethics committees, 10 personal commentators and one permanent observer. Only *one* Member State objected to any use of the term 'dignity' judging it too 'vague' (Macklin, 2003). Given the wide range of cultural and religious values represented, these results give evidence for a remarkable degree of agreement on the ethical and legal primacy of human dignity.

Such widespread agreement is particularly significant at this time for bioethics. Some bioethicists today are opposed to any use of the word 'dignity' in bioethics discourse. They take its use to be a covert way to introduce religion

into bioethical discourse, a move they find objectionable (Schultziner, 2004). Another source of objection comes from those who insist that assigning any special status to man in the biosphere is to be guilty of speciesism (Wilson, 1988). This is a major error in the eyes of certain Darwinian biologists. Others hold all life forms to be sacred and endowed with its' own 'dignity' equivalent to that of humans.

These objections notwithstanding, the UNESCO Declaration clearly assigns ethical responsibility to the only living creature to whom moral responsibility can be attributed. We do not assign moral blame to the tiger who attacks and maims his trainer. We do assign moral blame to the trainer if he abuses or mistreats the tiger. In practice at least, most people in the West base human dignity in the possession of reason and thus responsibility for past and future behaviour far beyond any of the rudimentary simulacra of thought in non-human species.

The Declaration treats dignity as an inherent property of being human. Thus it is independent of external attributes observers might consider as dignified or 'undignified' on the basis of a person's appearance, dress, behaviour, disease, etc. These are external estimates of 'worth' but they do not touch at all on the inherent dignity of all humans as humans. External observers attribute them to other humans, or humans may attribute them to themselves. These assessments of dignity or lack of it are imputed from 'outside.' They are measured in terms of social acceptance. External assessments are a reality in human relationships. But they are not to be confused with inherent dignity, which is the worth of a human being *qua* human being. This inherent dignity cannot be lost, however 'undignified' one may appear to others or even to oneself.

This inherent dignity is possessed in equal measure by every human and is the basis for the equality of humans as humans. Inherent dignity is the property of being human that generates the universal moral obligation to do good for, and avoid harm to, other humans. Fulfilment of that obligation is the basis for the principle of beneficence and non-maleficence. One may take beneficence and non-maleficence as separate principles (Beauchamp and Childress, 2001) or as one principle (Frankena, 2001). The end result is the same insofar as the aim of Article 4 of the Declaration is concerned.

More significant in the application of the principle in bioethics is the level of beneficence required to satisfy the obligation. Here Frankena's hierarchy of the meanings of beneficence becomes relevant. The lowest level of beneficence in his schema is really non-maleficence, that is the obligation not to inflict harm. In ascending order, the next level is to remove evil or

harm. Above that is the duty to prevent evil or harm. The highest level of beneficence is to promote good.

The level of beneficence obliged by the principle of beneficence is difficult to assign precisely. It depends on the circumstances and details defining the human interaction in question. It is obviously not limited to medical practice and research, but these are the venues that are most specifically the concern of the Declaration. Here the degree of vulnerability of patient or subject, the risks being run, and the personal needs of patients and subjects must all be factored into the assessment. Clearly the special obligations inherent in the roles of physician and investigator impose higher levels of beneficence.

In the case of ordinary medical practice, beneficence is the first moral precept of professional ethics, and has been for centuries. The specific purpose of the clinical encounter is the good of the patient – that is cure whenever possible, amelioration of disease, relief of pain, and care always. By virtue of the nature of his profession, the physician has committed his special skills to the patient's benefit, not his own. At a minimum, the physician's beneficence must go beyond simple removal, avoidance or prevention of harm. Positive good must be done to the degree possible since the patient is in need of help when he or she encounters the physician.

The physician's obligation to beneficence is binding even it means some significant suppression of his or her own self interest, for example danger of contagion, loss of time or income, or personal inconvenience. Heroic measures, like exposing oneself to certain injury or death, are not ordinarily required. Within the role-related scope of their duties, nurses, pharmacists and allied health workers are held to proportionate degrees of beneficence. Legitimate self-interests, such as family and personal obligations of other kinds, must be factored in as well.

At the heart of the matter is a prudential weighing of risks to both patients and physicians with the weight of responsibility resting with the physician or other health professional. The consent to be treated or to be an experimental subject is the patient's own to make as outlined in Article 5 of this Declaration.

MORAL SANCTION FOR PERMITTING RISKS OF HARM

Article 4 of the Declaration entitles all humans to an inviolable moral claim to freedom from intentional harm. The inviolability of this moral claim must, we know, be qualified, since in all medical treatments and in medical research the possibility of unintended harm is present. Absolute protection against

all harms is not attainable, even in ideal circumstances. Unintended, but possible and even probable harms must be tolerated in the use of any potent, established or new treatment. Without such risks neither could treatment be given nor research be carried out at all. Patients and society at large would be deprived of important medical advances.

The moral sanction for tolerating exposure to risks is the intended benefit that follows from the treatment, prevention or amelioration of illness and disease. Article 4 requires that the possibilities of harm are morally acceptable only if the maximization of benefit and the minimization of harm is a universal ethical requisite. Physicians and other health workers are therefore obliged to conduct the process of minimization and maximization itself in as efficient and morally defensible ways as circumstances will allow.

The same moral sanction exists for experimental medicine, namely the necessity of running risks if advances in medical treatment are to be validated by rigorous scientific clinical investigations. In the case of research, the process of maximizing benefits may be more complicated than in therapeutic medicine. Subjects of research may be victims of the disease in question and may therefore gain benefit from experimental use of a new medication. Under these circumstances patients may be overeager to run risks. The physician-investigator must be careful not to take advantage of the patient's vulnerability. However, other subjects may not be suffering from the disease in question. Instead they voluntarily subject themselves to risks so that essential pharmacological or physiological knowledge pertinent to the cure of disease in others may be obtained.

Conformity to the obligations implicit in Article 4 requires a combination of prudential judgments and technical competence, both of which require the most assiduous attention to their moral content. Prudence in the sense of Aristotle's *phronesis*, that is practical reason in choosing the most appropriate means to a good end, is therefore a necessary intellectual virtue for health professionals to cultivate.

CRITERIA FOR MAXIMIZATION AND MINIMIZATION OF HARM

Several methods are currently in use to discern how benefits can best be balanced against harms. These methods can be applied in the treatment of individual patients, in the conduct of clinical research and in devising public policies. They vary in their moral acceptability, reliability and fairness. A detailed comparative analysis is beyond the scope of this commentary.

However, it is important in implementing Article 4 to outline something of the nature of each method.

The key terms between and among which judgment must be made are benefits, harms, and risks (Beauchamp and Childress, 2001: 199–202). Estimates of probability and projections of the expected impact on an individual patient or society of a proposed treatment, experiment, or social policies must be made. Benefits are of several kinds: advancing the patient's or society's interests, producing new knowledge of value to future patients, or devising a policy which advances the common good. Risks are the estimates of the probabilities or possibilities of injuring a patient or a society, for example producing harms that violate the interests of patient, research subjects or the social order. Harms may be financial, physical, emotional, or spiritual, singly or in combination.

Methods for evaluating the ratios of harm and benefit are usually qualitative, probabilistic value judgments made by each of the participants – patients, health professionals, investigators, or policy-makers. For the most part these 'methods' are usually informal, qualitative and highly dependent on the personal values the participants attribute to the outcome. 'Values' represent those things participants deem worth living, working or even suffering or dying for. Attempts have been made with mixed success to formalize and to quantify harms, benefits and risk assessments under the rubrics of cost/benefit, cost/effectiveness, cost/utility, and cost/value ratios. For the most part with individuals there are qualitative assessments. Semi-quantitative methods most often are used not in individuals but in social decisions where it is presumed that quantification is more easily attainable. But in recent years there has been a growing tendency, usually economic in intent, to apply them to individuals as well.

One much debated assessment of benefits versus harms is the 'QALYs' method (Williams, 1995). This acronym stands for quality adjusted life years and purports to quantify the cost/utility ratio both for individual clinical decisions and for public policy determinations. Here the highly debatable judgment of quality of life is interjected. A semi-quantitative judgment is proposed in the balance between quality and quantity of life. The utility of the outcome is measured in terms of the number of years it is expected to last and its quality during those years.

Serious questions have been raised about the ethical propriety of the QALYs method. Among them are its obviously utilitarian bias, its attempt to quantify a qualitative criterion which is not measurable *per se*. QALYs are biased against the sickest and the oldest members of society. Similar debates circulate around attempts at quantification of the harms/benefit ratio. Each

proposal for risk assessment must be examined seriously, as well as critically. A prime criterion, if Article 4 is to be respected in spirit as well as in letter, is the ethical consequence of any method, however attractive it might be actuarially, statistically, economically or socially.

Here one must remember that Article 4 is preceded by Article 3, which unequivocally asserts that '…the interests and welfare of the individual should have priority over the sole interest of science and society'. Clearly, the Universal Declaration on Bioethics and Human Rights seeks to avoid, or mitigate, the tendency to technologize the whole of human life, that is to make a human being a statistic. Statistics and economics are essential in assessing ratios of harm to benefit. But ethics should always drive economics and politics, economics and politics should not drive or distort ethics. It is this distinction that grounds the clear recommendation of Articles 3 and 4 of the Declaration, giving priority to individuals over social good.

Much as economists, policy-makers and clinicians would prefer quantified criteria for measuring benefits against harms the likelihood for some time to come is that the process will remain an act of prudential judgment in the face of considerable uncertainty. This does not vitiate the central conception of Article 4. Rather it recognizes it as analogous to any difficult decision involving our understanding of what human life is about, and how best to live it, as well as to leave it. Articles 3 and 4 are ethical compass points whose violation would undermine both the Universal Declaration on Bioethics and Human Rights and the earlier Universal Declaration of Human Rights.

What is crucial to the assessments of harms and goods, or costs and risks, is the underlying concept of beneficence and benevolence. These essential concepts will shape the process of risk and benefit of a procedure and a treatment. What is at issue are the varying perceptions of the level at which benevolence becomes an obligation as schematized briefly earlier in this contribution. This estimate will vary often between and among physicians and other health professions, between patients and physicians, between society members and between society members and their policy-makers. An examination of these differences is needed in any interpretation of the implementation of Article 4.

BENEFICENCE, BENEVOLENCE AND THE CHARACTER OF DECISION-MAKERS

Article 4, like all ethical principles or action guidelines, must be actualized through individual human beings. How each participant in the decision

interprets the principle or action guidelines will depend on the kind of persons they are and therefore on their characters. If we take beneficence and non-maleficence as the ethical principle in question, the way it is applied in any particular case depends on the possession or absence of the virtue of benevolence. Benevolence is a character trait that habitually disposes one to do good. Beneficence, on the other hand, is the act that enables one to do good.

This point, and the distinction it encompasses, is crucial to the implementation of Article 4. It speaks not only to the principle but to the kind of person required to apply the principle optimally. Here the issue has become one of the education of future health professionals. The virtue of benevolence must be cultivated in all phases of a health professional's education. Attention to character formation has too often been neglected and replaced by indoctrination in principles and duties. These latter are important, but ultimately they will be actualized through the minds and actions of human beings. That the principles are perceived and interpreted with sensitivity is as important as knowing the content of Article 4 and how to apply it.

ARTICLE 4 AND ROLE-RELATED CONFLICTS

The clinical setting – conflicts in the implementation of Article 4

All of this becomes even more significant when we examine the personal conflicts experienced by health professionals attempting to apply their perception of the principle of beneficence and non-maleficence. More specifically, the character of the health professional, physician, scientist or physician scientist is crucial because there may be an inherent ethical conflict between and among these roles.

First is the conflict between beneficence and autonomy, both of which derive from the inherent dignity of the human person and must be protected. Here it seems most relevant to mention a fact often neglected, namely that the physician as well as the patient or research subject are entitled to respect as persons. For Kant, respect for autonomy is the most stringent of the obligations to protect human dignity (Kant, 1956: 98, 101–2). Since doctor and patient are both entitled to equal respect, neither can override the autonomous wish of the other. How this potential ethical conflict is managed is a central issue in clinical ethics today. It is more clearly defined in human experimentation under the aspect of consent in Article 6 of the Declaration. All investigators and subjects have been sensitized by the revelations of the Nuremberg Trials to the dangers of improper or uninformed consent.

In ordinary therapeutic relationships, the physician exercises the role of beneficence by accurate assessment of the patient's clinical conditions and needs, making them known and understood by the patient and/or the patient's surrogate decision-makers. The patient's right of autonomy is ethically expressed in the negative right of refusal of treatment or participation in an experimental trial (Pellegrino, 1994). The right to refuse, however, does not translate into the right to demand any kind of treatment the patient fancies. If the patient's request or choice violates the professional or moral integrity of the physician, the physician must refuse, politely but definitively, giving reasons for his action. The patient may discharge the physician, or the physician may ask to terminate the relationship after arranging for another physician to assume responsibility.

Much more can be said on what is becoming a major issue in end-of-life procedures and definitely involves application of the ethical injunctions of Article 4. The world's literature is expanding exponentially on this question. It need only be said that in the emotionally charged decisions about how to conduct one's own death, the responsibility to balance beneficence and autonomy must be fulfilled in the most morally responsible way.

In the long run, in the implementation of Article 4, the preservation of the human dignity of the physician, other health professionals and patients remains an ethical challenge. Inescapably, the character of all the persons involved in the decision will determine how authentically the letter and spirit of Article 4 are translated into action.

The research setting

In the research setting, the potential conflicts between autonomy and beneficence are in some ways simpler and in others more complex. They are simpler since so much attention has been directed to the regulation of experimentation in human subjects. Articles 5–8 of this Declaration attend to these issues. They are more complex when the subject is also a patient, since the moral dictates of the therapeutic relationships are intermingled with the non-therapeutic goals of scientific investigation.

The physician, who engages in human experimentation, receives his or her social and moral mandate from the fact that knowledge of human responses to illness and to attempts to treat it must receive its final test in humans. Models of illness and treatment, and animal experiments can serve the investigation in its early phases. For final validation, observations must be made in humans. This being the case, the physician must serve two goals

to implement the social mandate, which permits human experimentation. He or she must satisfy the canons of good science, and at the same time protect the dignity and human rights of the subject.

Caring for the patient and serving truth may come into conflict. When they do, the physician's function as a care provider must take precedence if Article 4 as well as Article 3.2 are to be respected. The physician's role as caregiver takes priority over that of scientist. The research protocol or the need for 'statistical power' must never endanger the subject.

Here the character of the physician investigator becomes highly relevant. He or she may be tempted to put the good of the experiment and its value to society ahead of the subject's welfare. The desire for academic advancement or visions of prestige and honour may obscure sensitivity to patient or subject risk. Articles 3 and 4 are unequivocal in resolving any such conflict on behalf of the patient over the putative benefits to society.

Patients suffering from diseases in which standard treatments are unsatisfactory are especially susceptible to being induced to run risks. Physician investigators must be guardians of the patient's interests despite willingness in patients to expose themselves. The same is true of normal subjects who do not suffer from the disease. They are vulnerable because they may be motivated to run risks for the good of others. No matter how much social good may accrue, the interests of the patient and the subject must always be protected.

PERORATION

Article 4 of the Universal Declaration on Bioethics and Human Rights is clearly, concisely and unequivocally designed to protect the inherent dignity and human rights of every human person. It is a direct correlate of the first principle of the Universal Declaration of Human Rights as it applies to the ethical issues arising in the application of biological knowledge to humans and human affairs.

The implementation of Article 4 rests on the maximization of benefits and minimization of harms to patients and research subjects whose interest and welfare should take priority over the interests of science or society. Health professionals therefore are enjoined to follow the principle of beneficence and non-maleficence, to make sensitive and ethically appropriate assessments of risks and benefits, resolve conflicts of interest and obligation with the aim of protecting human dignity, rights and freedoms. Only through faithful and authentic implementation of Article 4 can physicians, clinical investigators and health professionals satisfy the trust individuals and societies place on them.

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Chapter 7

ARTICLE 5: **AUTONOMY AND INDIVIDUAL RESPONSIBILITY**

Donald Evans

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.

SOURCES OF THE ARTICLE

Modern bioethics, which embodies medical ethics and health care ethics more generally, has emerged from a number of different contexts. Two of them might each claim to be the most notable stimulus for the emergence of autonomy as the ethical value which figures most prominently in both clinical practice and research at the beginning of the twenty-first century.

One of these contexts is the emergence of the notions of human and individual rights during the second half of the twentieth century. The other is the reaction to notorious abuses of human rights in the name of clinical research during the same period, in both the various arenas of the Second World War and subsequently in many countries in peacetime.

The classical expression of human rights is the Universal Declaration of Human Rights (1948) and the prominence of autonomy in that Declaration is evident at the beginning of the document. This fundamental article of the Declaration holds that all human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood. This Article also underlies many of the succeeding rights to: liberty (Article 3); freedom from slavery (Article 4); freedom from torture and degrading punishment (Article 5); protection from arbitrary arrest (Article 9); freedom from arbitrary interference (Article 12); freedom of movement (Article 13); seek asylum (Article 14); marry

voluntarily and found a family (Article 16); own property (Article17); freedom of thought, opinion and expression (Articles 18 and 19); freedom of peaceful assembly (Article 20); take part in government (Article 21); work (Article 23); choice of education (Articles 26); and participation in the cultural life of a community (Article 27).

The Universal Declaration of Human Rights followed hard on the heels of the Nuremberg Code (1947), which issued from the Nuremberg trials of medical researchers who were accused and convicted of committing crimes against humanity in the name of medical research. The first and most prominent recommendation of that Code concerns the issue of informed consent, which is the most tangible expression of respect for autonomy in medicine. It reads as follows:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity (Nuremberg Code, 1947).

The discussions of the expert group and the IBC in the evolution of the Universal Declaration on Bioethics and Human Rights constantly referred to the need to link bioethics with human rights, a link which had hitherto only been at best a sub-text in bioethics. The key to this connection was clearly the close connection between the fundamental guideline of the Code and the Universal Declaration of Human Rights noted above. It thus became clear to those developing the Universal Declaration on Bioethics and Human

Rights that an article enjoining respect for the autonomy of persons involved in medical treatment and research was an absolute requirement.

THE RESULTS OF THE EMERGENCE OF THE VALUE OF AUTONOMY IN MEDICINE

This rise to prominence of the concept of informed consent over the past 50 years has marked major changes in both clinical practice and medical research. The concept embodies respect for the autonomy of patients insofar as it requires practitioners to devolve to patients the responsibility for undergoing treatment and participating in medical experiments and other research.

In medical practice this change has led to the adoption of a patient-centred practice model as opposed to a paternalistic model of care. Now the patient is empowered to collaborate with the practitioner as the key decision-maker in clinical care rather than as the passive recipient of care designed, prescribed and imposed by the expert health care professional. This traditional passive role has been aptly encapsulated in the label 'patient'. The new model makes it impossible for the professional carer to identify responsibly the needs of the patient and the most acceptable programme of care without due consideration of the narrative of the patient. The patients' perceptions of their condition and situation, in consultation with the carer, is given centre stage as opposed to being peripheral to the clinical encounter. Whilst the practitioner remains the expert with respect to the medical matters, the patients are the ultimate arbiters both of what would constitute a suitable intervention and what would be a desirable outcome. For example, some effective measures such as blood transfusions or the use of porcine insulin might be ethically unacceptable to a given patient even though they would secure a desired outcome.

Similarly some outcomes, such as the amputation of a limb or the extension of life, might be seen as undesirable by a patient whilst they appear to be worthwhile to the practitioner. In these cases a patient's right to refuse treatment is a protection of their autonomy in that they are taking responsibility for the treatment decision. That is, the patient becomes responsible for commissioning the ensuing treatment and its intended benefits. The crucial difference from the paternalistic model is that the possibility of a disagreement between the clinician and the patient about what would constitute a health gain or an acceptable treatment becomes visible and significant in the provision of treatment.

A similar point can be made on the research front. Even the Nuremberg Code refers to those people upon whom research is carried out as the 'subjects' of the research. Nowadays the spirit of that Code has suggested that the term 'participant' is a more suitable label than 'subject', as the latter still suggests the role of passive recipient rather than research collaborator. The impressive development of systems of ethical review of research on human beings, which has evolved over the past 40 years, places processes of informed consent at the centre of the proper design of research protocols. This requirement is actually enshrined in law in many jurisdictions. The development of such systems in numerous countries was prompted by outrageous cases of abuse of human beings in research where their autonomy was totally disrespected. In two sample cases it can be shown that major steps in the development of ethical awareness in research were prompted by such cases.

First the Tuskegee Study in the United States in which hundreds of African Americans suffering from syphilis were, without their consent or knowledge, entered into a study of the natural history of the disease for 40 years without being offered treatment for the condition when it became available. Discovery of the study prompted the creation of Section 474 of the National Research Act Public Law 93-348, 12 July 1974, which demanded the setting up of Institutional Review Boards to review all publicly-funded biomedical and behavioural research involving human subjects 'in order to protect the rights of human subjects of such research'. Second, in New Zealand, on 5 August 1988, the Cartwright Inquiry reported on the *Carcinoma-in-situ* (CIS) scandal at the National Women's Hospital in Auckland in which large numbers of women, again without their consent or knowledge, were entered into a 20 plus year study of early cell changes in the cervix (Cartwright Inquiry, 1988). They were examined every year and the progress of the condition was monitored and recorded without the women ever being offered treatment, even long after the rest of the medical world was persuaded that such changes were precursors to invasive cancer. Many of the women developed invasive cancer and some of them died from the disease. That report recommended that independent ethics committees be set up to review all health research proposals involving human participants and all innovative treatments. It also recommended the creation of recognizable education in medical ethics for emerging doctors. The Government of New Zealand responded to the report by passing legislation that established the Office of the Health and Disability Commissioner, and its first incumbent developed a Code of Rights for Health and Disability Consumers.

THE EVOLUTION OF THE ARTICLE

It is interesting that in the First Outline of June 2004 no reference is made to the principle of respect for autonomy (IBC, 2004a). The Second Outline (July 2004), using a distinction between general or fundamental principles and implications of these principles, mentions autonomy as one of the implications, without further elaborating it (IBC, 2004b). The text of an article is provided in the Third Outline (August 2004):

> **Article 10 – Autonomy and responsibility**
> Any decision or practice within the scope of this Declaration shall respect the autonomy of a person as an expression of his/her liberty to make decisions without prejudice to the autonomy of others (IBC, 2004c).

The IBC Drafting Group in its fourth meeting, resulting in the Third Outline, had extensive debate on the distinction between fundamental and derived principles. Fundamental principles are basic principles that cannot be justified by another principle; derived principles can only be justified by one or more fundamental principles. The Group decided to keep the distinction. Autonomy continues therefore to be included in the category of derived principles, because it is based on the fundamental principle of human dignity. Discussion of the principle, however, focused on the balance between autonomy and the responsibility of the individual towards others. On the one hand, the draft text reflects the rights and the freedom of each person to make individual decisions, while on the other hand the autonomy of others needs to be respected. It should also be recognized that individual autonomy has different importance according to different cultures by reason of the place given to the family and to the community (IBC Drafting Group, 2004).

The Fourth Outline of December 2004 moved the article on autonomy and responsibility to the section on general principles. The text of the article was also reformulated and introduced the term 'responsibility':

> Any decision or practice shall respect the autonomy of persons to make decisions and to take responsibility for those decisions while respecting the autonomy of others (IBC, 2004d).

The Preliminary Draft Declaration, finalized by the IBC in February 2005, has exactly the same formulation (IBC, 2005). The governmental experts, meeting in Paris in June 2005, removed the reference to decisions or practices in the article. They also took out the word 'shall'. These changes, however,

were made for all relevant articles. The article on autonomy and responsibility as such did not raise any fundamental differences. Changes have been made in order to clarify that autonomy to make a decision should be respected, but at the same time responsibility for this decision should be assumed in any event. Some delegates underlined that it is important to add a phrase in this article in order to protect persons incapable of exercising their autonomy. Other delegates were of the opinion that the case of incapable persons could be dealt with in the article on consent. Eventually, a compromise was reached: a phrase referring to persons not capable of exercising their autonomy was added to this article, while a separate article (Article 7: Persons without the capacity to consent) elaborated the situation of such persons in regard to consent. After consultations, the meeting agreed on the text of the article, which was later adopted by all Member States (Report expert meeting, 2005).

EXPLANATION OF THE ARTICLE

Following the background from which this Article of the Declaration emerged, careful consideration of the notion of autonomy is required in order for the Article's significance to be understood. The notion is discussed below in four stages:

(i) the nature of the limits to which autonomy is subject;
(ii) the conditions under which autonomy can be exercised;
(iii) the manner in which the autonomy of persons can be respected when it is compromised by their condition;
(iv) the relation between communal and individual autonomy.

The limits to which autonomy is subject

Let us begin this reflection by noting that the right to exercise one's autonomy is subject to limits. However, these limits are highly restricted and are usually enshrined in law. Significantly the right can only be abrogated in rare circumstances, each of which involves the protection of the autonomy of others. Legally authorized personnel can arrest, question and imprison others for breaches of the law within carefully determined and proper limits. Medical personnel can compulsorily detain mentally ill persons for protection and treatment if they constitute a danger to themselves and/or to the freedom and safety of others. Similarly, those who suffer from very serious infectious diseases may be compulsorily removed from their place of abode or work to protect the health of others. Such justified restrictions of the liberty of people to choose for themselves are very few and highly constrained.

These constraints are designed to ensure that those who exercise these extraordinary measures do not abuse the liberty, and hence the autonomy of citizens. In the medical setting they are designed to ensure that medicine is not used as a form of social control unrelated to the health and wellbeing of people. An example of this abuse was the cause of the required withdrawal of Russian psychiatrists from the World Psychiatric Association some years ago. The contrived diagnosis of 'sluggish schizophrenia' was used to detain and forcibly treat political dissidents whose deviant political views were regarded as portents of potential symptoms of schizophrenia. The diagnosis was discredited by psychiatrists in the rest of the world and demonstrated to be a means of using medicine as a tool of social engineering unrelated to health issues. The matter was successfully resolved when employment of the diagnosis and the resultant interventions were abandoned by this group of practitioners who were then restored to the World Association.

The conditions under which autonomy can be exercised

The freedom to make authentic decisions depends on the *ability* to make such decisions. People lacking this ability are often referred to as being incompetent. Various groups of people have been traditionally labelled in this way. They include people with learning difficulties, the mentally ill, children, patients in shock, confused elderly and unconscious people. The criteria used to identify these groups have included: the ability to understand the issues involved in the decisions in question; the ability to evaluate these rationally; a reasonable outcome of the decision; and evidence of a decision being made. While these look like objective criteria, there are difficulties in their application. Inevitably the assessment of any judge of the competence of others is made from the judge's perspective of what it is to understand, what is rational and what a reasonable outcome would look like. But there might be disagreement about each of these. For example some people might be risk-takers, and what appears to be rational to them would not appear so to a cautious judge. People might also disagree about what constitutes a reasonable outcome of a decision. Some people would demand a more detailed grasp of facts than others in accepting that a decision-maker understands a situation. Care must therefore be taken not to demand too high a standard in applying the criteria, otherwise the autonomy of decision-makers might be undermined simply because they wish to decide differently from their judges. The standard safeguard employed is that no judgement of competence is

called for unless there is evidence to undermine the normal assumption that decision-makers are competent.

However, even where the competence of patients or potential research participants is not in question, it is clear that where there is no adequate provision of information to a patient or a potential research participant, the circumstances preclude the possibility of informed consent. The adequacy of the information is well described in the Nuremberg Code's recommendation quoted earlier. It might be said that the qualification of consent with the word 'informed' is unnecessary as consent given in ignorance of what is being consented to cannot be genuine. This is true. However, the phrase 'informed consent' has been introduced to counter the practice of employing a formal consent process as a convenient protection for practitioners whilst concealing, or at least failing to disclose, sufficient information for the patient to make a reasonable decision. It is crucial therefore that sufficient information is given in a form, which is understandable to the patient or research participant, in order for their autonomy to be respected.

The manner in which the autonomy of persons can be respected when it is compromised by their condition

There are a number of cases where the autonomy of decision-makers is apparently compromised by their condition. These conditions need to be described with care. For example, it might appear that children, by their very nature, are incompetent because they cannot think like adults. This is certainly true of very young children, but as children develop they might show marked differences from each other. Fixing a chronological age such as 16 years to mark the attainment of competence is unsafe. The United Nations Convention on the Rights of the Child (UN General Assembly, 1989) asserts that children have the right to say what they think should happen when adults make decisions that affect them and to have their opinions taken into account (Article 12), have the right to get and share information (Article 13), have the right to think and believe what they want and practice their religion as long as they do not stop other people enjoying their rights (Article 14), and have the right to privacy (Article 16). All these assume that they have certain levels of competence. As they develop it should be the degree of their maturity which determines when they are regarded as fully competent and capable of autonomous decisions. This will vary from child to child, but to set higher standards of rationality and understanding for children than we do for adults would be contrary to respect for their rights.

It is also unsafe to regard people with learning difficulties as being incompetent by definition. Whilst people with this problem might not be autonomous with respect to certain kinds of decisions, they might well be so with respect to others. It will depend on the complexity and seriousness of the decision. Similarly, people with mental illnesses might be capable of making autonomous decisions at some times and not at others, or in certain phases of their illness be capable of autonomous decisions about some issues and not about others. In all these cases the crucial safeguard of respect for autonomy is that lack of competence is determined independently of the decision which the persons wish to make, otherwise, once again, the judgement of incompetence might simply be a reflection of a difference in perception between the judge and the decision-maker of what is a good decision.

In the case of the mentally ill, confused or unconscious, it might be possible to construct a set of authentic values out of their life histories in consultation with friends or relatives, which could guide decision-making on their behalf when they are incompetent. Such decisions have been labelled 'substituted judgements' in that they approximate as near as possible to a decision of the person concerned when that person is not capable of making a decision. They are not proxy judgements in which another person provides consent according to their own values. The formation of substituted judgements is a means to respecting a person's autonomy, even when that autonomy is compromised.

The relation between communal and individual autonomy

There is a difficulty in aligning the autonomy of individuals, which is embodied in this Article, with certain cultural settings where communal autonomy might be thought to prevail. But is it clear that either individual or communal autonomy should be preferred one to another? It depends on the kind of decision which is at stake. For example, as a member of a particular cultural group, a person might be approached to engage in a research project or a commercial enterprise which would provide access by the researchers or the business in question to materials or matters which might be seen as belonging to the group rather than to any individual in that group. Sometimes matters of this kind are referred to as traditional knowledge, and materials of this sort as cultural treasures. It follows that it is not the prerogative of an individual member of that group to profit individually from communal treasures or to betray such privileged knowledge to strangers without the consent of the

group. In such cases, such as the exploitation of indigenous flora or fauna, communal autonomy would impose proper limits on individual autonomy.

However, such cases should not be used as a basis for concluding that cultural considerations can dictate that for members of some groups communal autonomy can always override individual autonomy. For example a community might be prepared to permit researchers from outside their membership to conduct research on the possible causes of the prevalence of diabetes in the community. This might involve *inter alia* the collection of tissue from members of the group for genetic analysis. However, no individual member of that community should be obliged to offer himself or herself as a research participant in the study. An individual member of the community might voluntarily devolve the authority to decide for him or her to the community, but this would not undermine respect for his or her autonomy. However, if he or she did not wish to provide tissue for genetic analysis, the communal permission for the research to proceed should not preclude the possibility of his or her refusal to be part of the study. This is the import of Article 12 in the Universal Declaration on Bioethics and Human Rights, which asserts that respect for cultural diversity and pluralism should not be used to infringe on fundamental freedoms nor any of the principles set out in the Declaration, including Principle 5 with which we are here concerned. The scope of respect for individual autonomy cannot be limited by cultural considerations except where cultural knowledge and cultural treasures are involved. Such unauthorized limitations would constitute disrespect for fundamental freedoms.

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Chapter 8
ARTICLE 6: **CONSENT**

Regine Kollek

Article 6 – Consent

1. *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.*
2. *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. 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.*
3. *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.*

THE IMPORTANCE OF THE DOCTRINE OF INFORMED CONSENT

The doctrine of informed consent is one of the most well known elements of medical ethics and bioethics today. In essence it states that any preventive, diagnostic or therapeutic medical intervention as well as scientific research involving human subjects is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. Furthermore, consent should, where appropriate, be given, and may be

withdrawn, by the person concerned at any time and for any reason without disadvantage or prejudice.

Since medical treatment or research may pose risks to patients or human subjects, they have to be protected from unwanted and unwarranted interventions. Individual consent therefore is an indispensable prerequisite for medical care or biomedical research. It is an expression of respect for autonomy and self-determination. The importance given to this doctrine today is reflected by the fact that virtually all international agreements on ethical and legal standards in medicine and biomedical research endorse the requirement of consent or informed consent. Examples of international instruments that list informed consent as one of the key principles of biomedical research are: the World Medical Association (1964), the Council of Europe (1997), the Council for International Organizations of Medical Sciences (CIOMS) (2002), UNESCO (1997, 2003, 2005), and the Council of Europe (2005).

However, this global recognition of informed consent as a condition *sine qua non* for regular and experimental medical interventions is a relatively new phenomenon. Historically, it is by no means self-evident that a patient or research subject has to be informed about such interventions and to be asked for consent.

Historical background

The history of informed consent is manifold, culturally diverse, and rather controversial and cannot be 'reduced to linear narration of social events and practices' (Faden, 1986: 60). What seems to be clear, however, is that the concept of informed consent and its evolution is tightly connected to the physician-patient relationship and the way it developed through the centuries. The history of informed consent reflects these changes. Furthermore, the idea that patients should be asked for consent is also closely linked to a secular conception of medicine, which did not develop before the sixth or fifth century of our time in ancient Greece. Before, illness and disease were perceived as caused by evil spirits or punishment for a life not in conformity with the orders of the gods. Medicine then was part of the religious sphere, and healing was considered a magic practice only to be performed by initiated persons. Following the commands of a healer without questioning them was considered part of such practices and an essential precondition for succeeding.

In parallel to the emergence of a more materialistic understanding of disease the first explicit conception of medical ethics can be located. It has

been traced back to Hippocrates, one of the founders of this new secular and empirically based medicine. According to this 'Hippocratic Oath' physicians were obliged to act for the benefit of their patients and to avoid harm. However, this did not entail the obligation to tell the truth to their patients. On the contrary, sometimes it was considered harmful to be to outspoken about their disease, its treatment and prognosis. The physicians regard themselves as knowing best what is good for the patients. In western countries, such paternalistic conceptions of the doctor-patient relationship prevailed until the second half of the twentieth century. In contrast to paternalism, modern conceptions of the physician-patient relationship are characterized by individualism and autonomy. The physician acknowledges that it is the patient who finally authorizes interventions on his or her body. In Western countries, this change is at least in part the result of the social emancipation movement of the 1960s and 1970s with its strong rejection of authoritarian structures in all dimensions of societal life (Fox, 1990).

Obtaining consent for necessary treatment in case of painful and/or progressing illness is but one part of the history of consent. The other much more recent and controversial part of this history is related to systematic medical research involving healthy volunteers or patients. Such research became an important part of medical practice in the second half of the nineteenth century, when scientific and experimental methodology was introduced into clinical medicine, and large hospitals were established. Often, research was done 'in the service of science and medical progress' without the consent of the patients. After it became known that some people suffered injury and harm from non-therapeutic interventions, the ethics of human experimentation became a public and political issue. The first detailed regulations about non-therapeutic research, which set forth the legal basis for disclosure and unmistakable consent, were issued in Germany in 1900 (Vollmann and Winau, 1996).

However, it was not before the horrific crimes of the Nazi doctors became known, and the publication of the Nuremberg Code in 1947, that the moral duty of physicians and researchers to obtain consent became more widely recognized. In 1964, the *Ethical Principles for Medical Research Involving Human Subjects*, strongly emphasizing the need to obtain informed consent for medical treatment and research, became adopted by the General Assembly of the World Medical Association in Helsinki (World Medical Association, 1964). Today, the doctrine of informed consent has been widely accepted in both clinical practice and biomedical research.

Fundamental importance of consent

The doctrine of informed consent represents an essential ethical and legal requirement for medical interventions that protects patients and their fundamental rights to integrity and self-determination. These rights are part of human rights, which have been affirmed by the majority of the countries in the world (Conference on Human Rights, Vienna, 1993). In ethical terms, the requirement for informed consent is based on the principles of 'respect for persons' and 'respect for human dignity'. They denote that a human being must not be used merely as a means to an end. Instead, one should not act against their wishes, respect their autonomy, their capacity to consider options, make choices, and act without undue influence of others.

It is important to note that the necessity to obtain informed consent for medical interventions and medical research on human subjects sets limits on the ability of the state, of medicine and the community to govern the individual. No interference into the human body must be undertaken without the permission of the person concerned. No matter how much the family or the wider social group may be involved in such a decision, ultimately it should be the right of the individual person to decide.

The rights to integrity and self-determination, however, are not the only justifications for the requirement of informed consent. For example, the duty to inform subjects about key aspects of a treatment or clinical trial can also be justified by the requirement of common decency or minimal respect, which we owe other persons because they are human beings. Since most people do feel violated if others interfere with their bodily integrity without consent, it can also be argued that the necessity to obtain consent has anthropological roots, which are at least to a certain extent independent of social and cultural circumstances.

The requirement of consent is of fundamental importance for the protection of the most basic rights of a person in the context of medical treatment and research. However, it also protects physicians against accusations and litigations, and opens up a legitimate domain of biomedical research. Today, informed consent has become 'the modern clinical ritual of trust' (Wolpe, 1998).

Evolution of Article 6 and its wording in the Declaration

The requirement for informed consent is put down in Article 6 of the Declaration, which evolved in several steps. Since the requirement is universally acknowledged, the IBC thought that it should be stated in a very

simple fashion. In the third public outline of the draft Declaration (IBC, 2004a), therefore, the article on informed consent only contained two short paragraphs on consent. The first one stated it as a common requirement for all fields of medical action; the second one referred to persons not capable of giving valid consent.

In the course of further discussions it was found important, however, to describe the elements of informed consent in more detail. The fourth public outline therefore introduced the requirement for 'ongoing participation of [the] person' in the provision of consent for medical diagnosis and treatment, believing that giving consent is an interactive process in which the subject should take an active role from the beginning to the end of the research project (IBC, 2004b). This procedural conception of informed consent was considered important by the IBC but was not fully supported by the IGBC. In the final draft it was omitted and hence does not appear in the declaration endorsed by the General Conference.

The final version of Article 6 comprises three paragraphs. The first one states in positive terms that any medical intervention requires the prior, free and informed consent of the person concerned, based on adequate information. The second paragraph specifies the information that has to be given to the research subjects and how it has to be given. It also contains a statement on exceptions. The third paragraph makes a statement on the requirements for informed consent if research is carried out on a group of persons or a community. In such cases additional agreement of the legal representatives of the group or community concerned may be sought. This last paragraph in Article 6 represents an innovation in the conception and scope of informed consent. It acknowledges that in some communities or cultures it is customary that the social authorities decide whether a specific research project is acceptable for the community as a whole before they approve that members participate as individuals in such endeavours. However, the paragraph also makes clear that in no case a collective community agreement or the consent of a community leader or other authority should substitute for an individual's informed consent.

In summary, despite different changes, most of the substance of the principle drafted by the IBC has found its way into the final document. Research with persons without the capacity to consent, which was part of the article on informed consent in earlier drafts, is now regulated in Article 7. However, this is a matter of detail. The new Article 7 replaces an older paragraph but is more elaborate and more specific on particulars, and will be dealt with elsewhere in this volume.

THE MEANING OF THE ARTICLE

Despite the broad acceptance of the doctrine of informed consent, its meaning is not always clear; different interpretations are possible. In the Declaration and in general bioethical reasoning, it is also accompanied by a number of other principles and provisions; therefore it has to be interpreted and weighed in relation to them. Because of its centrality and complexity, the doctrine has challenged numerous scholars to elaborate on its meaning and significance. These extensive discussions in the literature on medical ethics and bioethics have enriched our understanding of the doctrine, which can only be interpreted if one takes these discussions and these uses in other documents into account.

The context of the text as a whole

In the context of the text of the Declaration, a distinction can be made between three types of principles: first, principles directly related to human dignity; second, principles concerning the relationships between human beings; and third, principles governing the relationship between human beings and other forms of life and the biosphere. Informed consent belongs to the first type of principles.

It can be said that the requirement of informed consent incorporates two aspects, which are two sides of the same coin. Evidently, it is an expression of the respect for autonomy and self-determination. At the same time, by being actively involved in the process of decision-making and committing itself to one specific act, it is also a process by which the individual itself expresses and practices autonomy. Therefore, Article 6 on informed consent is directly related to Article 3 (Human Dignity and Human Rights) and to Article 5 (Autonomy and Individual Responsibility) of the Declaration. None of these Articles stand alone, they have to be seen in conjunction with each other, expressing different dimensions and aspects of central normative demands.

There is another connection which can be drawn between Article 6 and other Articles of the Declaration. Although consent is the expression of an individual decision, this decision should not take into account individual interests and needs only. Rather, it should consider the needs and interests of others too, who could be affected directly or indirectly by the consequences of this decision. This connects individual consent to social responsibility. Although it is true that the individual is responsible for itself in the first line, there are also relations with, and therefore moral obligations towards, others: the family, the wider social group, and finally humankind. This thought is

taken up, although indirectly, in Article 13 (Solidarity and Co-operation). It encourages solidarity and co-operation, which can, for example, be practiced with patients affected by a specific disease by participating in clinical trials exploring new drugs or donating tissue samples for basic research.

However, the notion of responsibility does not only refer to patients or research subjects, but also to health care professionals involved in processes requiring consent. This connects Article 6 to Article 18 (Decision-Making and Addressing Bioethical Issues) and to Article 19 (Ethics Committees). Article 18 points to the responsibilities of health care providers to promote and to adhere to professional standards. Article 19 widens these responsibilities by calling for the establishment of independent, multidisciplinary and pluralist ethics committees, which are in charge of the assessment of the conditions and consequences of biomedical research in general.

These elaborations show that there are more or less direct connections between Article 6 and several other Articles of the Declaration. This interrelationship and complementarity is underlined by Article 26 of the Declaration, which states that each principle has to be considered in the context of the other principles.

The context of other relevant texts

The first document of international relevance after the Nuremberg Code which took up the requirement for informed consent was the Declaration of Helsinki of the World Medical Association (1964). Although legally not binding, it gained great importance because it was the first international agreement of health care providers on professional standards.

The first time when the doctrine of informed consent became part of a legally binding international instrument was in 1997, when the Convention on Human Rights and Biomedicine was adopted by the European Council (Council of Europe, 1997). The convention refers to informed consent in Article 5 and 6. In 2000, the doctrine also was taken up by the Charter of Fundamental Rights of the European Union (Article 3). In 2001 the European Union adopted a 'Directive on clinical trials', which is binding in law in the countries of the Union since 2004.

In the context of UNESCO, the requirement for informed consent was first codified in the Universal Declaration on the Human Genome and Human Rights, which was adopted by the General Conference of UNESCO in 1997. In this Declaration, Article 5 shortly describes the requirement of informed consent, and Article 9 the conditions under which it may be

limited. Even more emphasis on the doctrine was put in the International Declaration on Human Genetic Data of 2003. Here, Article 8 deals with different aspects of informed consent, Article 9 with withdrawal of consent, and Article 10 with the right to decide whether or not to be informed about research results. In 2002, the 'International Ethical Guidelines for Biomedical Research Involving Human Subjects' were prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the WHO, which elaborates extensively on the different aspects of informed consent in several articles.

The appearance of the doctrine in relevant international documents underscores the importance of informed consent not only for contemporary bioethical thinking, but also for international policy and jurisdiction. The latter is emphasized by the European Court of Human Rights in its ruling on the case of Natallie Evans against the British Government, based on the Convention on Human Rights and Biomedicine of the Council of Europe (1997). In essence, the court rules that informed consent (or the withdrawal of it) cannot be overruled by competing interests.

The case: Prior to IVF-treatment, Ms Evans and her partner both signed a form consenting to the treatment and stating that it would be possible for either of them to withdraw their consent at any time before the embryos were implanted in the applicant's uterus. Before the embryos could be transferred the relationship ended. The former partner of Ms Evans withdrew his consent to the use of the embryos. She brought proceedings before the British High Court seeking, among other things, an injunction to require her former partner to restore his consent. Her claim was refused. Later on, the European Court of Human Rights supported the decision of the legislature not to allow for the weighing of competing interests in the circumstances of each individual case. To have granted a power to other authorities to override the need for a donor's consent would not only have given rise to acute problems of evaluation of the weight to be attached to the respective rights of the parties concerned, but would have created 'new and even more intractable difficulties of arbitrariness and inconsistency' (European Court of Human Rights, 2006). Such rulings confirm the juridical importance of the doctrine of informed consent, which ultimately rests on ethical foundations.

APPLICATION OF THE ARTICLE

Although the requirement for informed consent is widely acknowledged, considerable lack of clarity exists when it comes to the question of how

the Article can or should be applied in practice and in various contexts of application. In order to clarify this issue, elements of informed consent will be identified and questions arising in different contexts of application will be discussed.

Elements and procedures of informed consent

Consent is not a single act. It is but the last step of a process, which involves at least four steps (Beauchamp and Childress, 2001: 57).

a) Disclosure of information to the subject: The first step in the process of obtaining consent is the provision of information. Content of this information, as well as method, timing and setting of its provision, are of overwhelming importance. Disclosure of information involves practical problems concerning the amount and complexity of information provided. For some participants, even simple protocols may be too complicated and too extensive. Formalized and lengthy documents may ask too much of patients and undermine motivation to participate. Secondly, subjects may not be familiar with basic concepts of research and study design elements like randomization or control group. Thirdly, obtaining consent is not only sought out of respect for individual autonomy, but it is also a legal cover for health care providers. Therefore, different information may be relevant for health care providers than for patients or research subjects. And finally, extensive descriptions of uncertainty concerning best treatment may undermine trust.

b) Understanding of information: In order to give valid consent, the individual must have the capacity to understand the information given to her or him. This generates a fundamental problem for research in children or persons without the capacity to consent. This issue will be dealt with in a different chapter of this volume. However, comprehension can also be problematic if information given to the subject is concerned only with medical aspects and therefore may be one-dimensional and not sufficient for understanding and informed decision-making. Other dimensions, for example values held by the prospective participant, have to be considered as well. Furthermore, information relevant to behaviour and decision-making may differ from case to case. And finally, it is difficult to assess whether the patient or subject has indeed understood the information given. Although some efforts have been made to develop measures of informed consent and choice (e.g. Marteau, Dormandy and Michie, 2001; Michie, Dormandy and Marteau, 2002), more research is needed to soundly evaluate comprehension.

c) Voluntariness of decision: The person must be able to decide freely whether he or she wants to be treated in a certain manner or participate in research. He or she must not be subjected to undue influence or intimidation. Furthermore, he or she must be free to withdraw from consent at any stage, especially of research, without suffering prejudice or disadvantage. There are several factors which may affect a person's ability to decide freely. Significant differences in social status between prospective participants and researchers may affect willingness to ask questions and may also affect freedom to decline from taking part in research. Asymmetric relationships between medical personnel and patients may prevent prospective patients from expressing uncertainty, and social expectations of the family or community may force participants to take socially desirable choices. Finally, especially in poor countries, economic benefits may act as significant incentives and hence restrict indirectly voluntariness.

d) Formal consent: It is widely accepted that consent, at least to participate in research, must be explicit. This means that the consent form has to be signed, or an oral statement has to be given in the presence of a witness. In '*first person consent*' the participant him/herself gives consent. However, this may not be appropriate or acceptable in all cultures or groups. In some communities there may be a necessity to consult social leaders before asking individuals. Here the question arises whether this represents a case of inappropriate paternalism and neglects the right of a person to make her own choices, or whether such a practice is in accordance with the required respect for personal autonomy. In '*proxy consent*' the right to give consent to research is granted to social leaders, marital partners, senior family members, or community leaders. They may have authority to give consent on behalf of others. However, it is being debated whether such proxy consent involves the danger that participants are enrolled in clinical research against their will, and it therefore is in conflict with the fundamental principle of respect for persons.

Different practical context of application

Although informed consent has been widely accepted in ethical discourse, its practical application in different medical, social and cultural contexts poses several challenges. In the medical context, the application of the doctrine may differ in treatment and research. Consent for treatment is generally regarded as less critical, since the patient is in need of help and often does not have much choice. Although the patient must in principle consent to

treatment and have the right to refuse it, in most cases implicit consent may be sufficient. With respect to consent for research, different types of research have to be distinguished. Whereas clinical research may involve physical risks for patients and subjects involved in such studies, this is, for instance, not the case in epidemiological or biobank research.

Up to now, informed consent has mainly been relevant in the context of clinical studies designed to test new drugs and to analyze the patient's response to it. In such cases, the patient is directly affected and consent usually is sought for clearly defined and limited research purposes. In research on human tissue samples, which is usually done to generate basic knowledge or for public health purposes, the individual is not directly or physically affected. In the context of such research, the paradigm of obtaining specified consent is increasingly regarded as dysfunctional (Lunshof, 2006). Since samples are needed for future research and projects cannot be defined clearly at the time consent is being sought, it would be costly and time consuming to obtain qualified individual consent for each new research project. Furthermore, in some areas of medicine, like for the selection of health policies or the provision of public health, informed consent is considered to be useless (O'Neill, 2003).

Together with new research priorities, objectives and strategies, a competition emerges between two concepts which differ with respect to the meaning and primacy of autonomy. In the context of *individualism*, individual rights and interests are regarded as most important because they limit the ability of the state, the community, or family to govern the individual (Engelhardt, 1996). In the context of *communitarian* concepts, individual rights are regarded as secondary to the needs of the community or the state, who has the obligation to guarantee law and order, stabilize social structures, set health policy goals, and so on (Callahan, 2003).

First attempts to develop a new normative framework have been made (Knoppers and Chadwick, 2005). It questions the primacy of the current individualistic model and emphasizes communitarian values and principles like reciprocity, mutuality, solidarity, and citizenry instead. The aim is to find a balance between protecting the individual on the one hand, and enabling research for the benefit of society on the other (Knoppers and Chadwick, 2005). Whether and how this can be achieved is currently under discussion. It certainly would be a problem to ask the individual to waive his or her rights without establishing legal safeguards in addition to ethical ones. Initiatives to simplify over-boarding bureaucracy and laborious procedures, which may be a hindrance to science, are welcomed. At the same time, however, one has

to avoid that well-founded interests and rights of the individual are traded off for the interests of society, research and economic development.

The different cultural contexts of application

Beyond the practical context, application of the doctrine may also be shaped by the cultural context in which it is applied. The term 'culture' refers to the capacity of human beings to classify, codify, and communicate their experiences symbolically. More generally, it refers to patterns of human activity and the symbolic structures that give significance to such activity. Therefore, different cultures reflect different ways to signify and to evaluate human activity. Religions, values, political systems, social structures, appreciation of different professions, relation between the past and the present, the older and younger generations, families and individuals, men and women, doctors and patients and so on belong to the factors which characterize a specific culture.

With respect to the application of informed consent in different cultural contexts, we are confronted with the challenge created by the fact that the doctrine is culturally bound. Like medical science and technology and the ethics designed to deal with their impact, it is very much shaped by liberal individualism, which has its roots in Western culture (Pellegrino, 1992). For example, in Western culture, beliefs about personhood and autonomy inform every aspect of medical transactions, including the notion of informed consent. The individual is the locus of decisional capacity, and informed consent is regarded as an expression of personal autonomy. The concept of individual autonomy is deeply embedded in Western thought and philosophy. The preoccupation with these concepts in Western bioethics is indicative of the extent to which cultural values influence our orientation to biomedical morality. However, individualist assumptions underlying these concepts may not have universal applicability, even in Western settings (Barrett and Parker, 2003). They may be meaningless in societies that stress the overriding importance of an individual's relationship with family and community, or that express decisional capacity socially, and not individually.

To a certain extent, these challenges posed by different cultural understandings of informed consent have been appreciated by the Declaration. Paragraph three of Article 6 states that if research is 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. This may be the case if, for instance in genetic population studies, the genome is regarded as common

heritage of a group which is not at the disposal of an individual alone. However, in no case should such an agreement substitute for an individual's informed consent. Paragraph three also pays tribute to the empirical fact that in developing countries individuals may be especially vulnerable to exploitation, and therefore the requirement to seek additional consent from social leaders may be an important mechanism of protecting and enforcing their rights.

Although it is increasingly recognized that different strategies of application of the doctrine of informed consent are needed, there is little agreement about what processes and documentation are appropriate in varying cultural and social contexts. The challenge is to establish procedures that are both ethically sound and culturally sensitive, although there may be times when these two requirements appear to be in conflict. One way of resolving such situations is through careful and sustained community involvement in research (Lindegger and Bull, 2002).

CONCLUSION

Informed consent provides assurance that patients and others are neither deceived nor coerced (O'Neill, 2003). Quality information and voluntary consent are precautions against unwanted and unwarranted interventions on an individual's body. They are at the very core of modern medical ethics, which emerged as a reaction to unethical medical interventions and experiments from the very beginning of the twentieth century. The question is how this doctrine endures and further evolves under different practical and socio-cultural conditions. Certainly there are margins which can be used for the design of different approaches and procedures of informed consent. How this can be done is a matter of continuing research and evaluation of practice. Community involvement is an important element to incorporate cultural specificities into a concept that originally evolved in the context of Western medicine.

However, it must also be borne in mind that traditional cultural values which are rooted in the past may not be appropriate to solve problems which are posed by current and future technologies and developments. In a global perspective, modern medical treatment and research is more dominated by professional culture than by local or regional culture (Turner, 2005). This is not only true in the West, but everywhere in the world. The challenge is to develop a global culture of medical treatment and research, which respects the rights and the interests of the individual, without disregarding

local social and cultural values and without undue impediment to research. However, the order of precedence must be clear: the interests of medicine and society must never prevail over the interests of the patient. Ultimately, in modern secularized medicine, informed consent is the touchstone of an ethical physician-patient relationship. If the well-being of the patient is at the foremost interest of the physician, informed consent must be an indispensable part of this relationship.

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Chapter 9

ARTICLE 7: **PERSONS WITHOUT THE CAPACITY TO CONSENT**

Jean F. Martin

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.*

BACKGROUND

The notion of capacity in a legal sense probably appeared with the earliest codifications of law like rules. As a society structured itself, it designated within it people or groups with different types of rights and prerogatives. To take an example, in Ancient Rome, only a minority of persons were Roman citizens and could take part in decisions of a political nature. In the Middle Ages, noble classes ruled over their countrymen. Closer to our topic, the testimony of women was not accepted in courts – or did not have the same weight as that of men – in past centuries. Children's testimony had no validity

in European courts up until the nineteenth century. In fact, women remained in several respects *legal minors* in many European countries until the twentieth century, and they needed the consent of their husband to sell goods, including their personal possessions. Even today, in a number of regions, women remain legal minors. Regarding health care and research, the situation of persons without the capacity to consent has been part and parcel of the bioethical discussions and regulations, particularly following World War II and the Nuremberg Code. It is a classical theme, about which the deontological as well as the legal dispositions still vary from country to country.

A major philosophical issue is related to the differences in attitudes – and ulterior conclusions drawn – between so called deontologists for whom the application of the rules and principles is paramount, and utilitarians or consequentialists, for whom the consequences of what will be decided is granted significant weight. This leads to important societal debates, for example with regard to handicapped persons. From a deontological perspective, the meaning of life for these persons is based on their intrinsic value and dignity; from a utilitarian perspective, this dignity is based on the evaluation of the person's 'welfare'; the quality in particular of the person's autonomy is determinative for his or her dignity (Cassiers, 2001). Others, however, underline that it is important to defend that dignity is not dependent on the quality of a person's autonomy. This view is expressed in a recent book of the former President of the French National Consultative Ethics Committee (CCNE):

> Is our emphasis on autonomy not disregarding the fact that human dignity resides in a permanent tension between the individual and the collective, with the reciprocity of recognition which makes that the subject exists only in a certain social context?… Dignity resides in the attention shown to others (Sicard, 2006: 14–15).

THE LEGITIMACY OF RESEARCH INVOLVING PERSONS WITHOUT THE CAPACITY TO CONSENT

At a conference in Paris in 2005, convened by the French National Commission for UNESCO, the president of the Steering Committee on Bioethics (CDBI) of the Council of Europe commented on the Universal Declaration on Bioethics and Human Rights, and particularly Article 7.

> The most burning question of medical research in regard to human dignity concerns undoubtedly research with persons incapable to

> consent … Of course, there are exceptional situations justifying research without direct potential benefit to be carried out with groups of persons without the capacity to consent, for example to better understand the metabolic functions of newborns. Similar situations concern victims of accidents or the mentally ill. Although history has provided us with sad experiences of abuse… it is not desirable to completely prohibit this type of research… But it should be strictly regulated in domestic law. Anyway, one needs to be conscious of the difficulty to find a balance that is satisfactory for research as well as for persons to be protected (Doppelfeld, 2007: 84).

Doppelfeld notes that Article 7(b) formulates criteria similar to those included in the 1997 Convention on Human Rights and Biomedicine of the Council of Europe (Article 17). Furthermore, he wishes that one would clarify that the protection granted by Article 7(b) could not, in any circumstance, be subjected to limitations as made possible by Article 27 of the Universal Declaration on Bioethics and Human Rights. He concludes with a comment about public health as a criterion for the evaluation of relevant interests: 'Public health is explicitly mentioned … as a possible justification for limiting the rights of the person. Even if these limitations are perfectly justified when diagnostic and therapeutic measures in relation to epidemiological risks are concerned, they are on the other hand more problematic in the area of medical research' (Doppelfeld, 2007: 85). He underlines that, as a counter-weight to relativism, it is necessary to promote in bioethics an 'organized vigilance'. Speaking at the same conference, the Polish Judge Marek Safjan supported explicitly the content and, with a few remarks, the wording of Article 7 (Safjan, 2007).

In a Message to Parliament about a new proposed article about research on human subjects in the Federal Constitution, the Swiss Government points out that: 'The fact that risks and constraints should be minimal means that the research project might cause only an insignificant and transient alteration of the health status (risk) and only transient and negligible symptoms or inconveniences (constraints)' (Switzerland, 2007). It goes further in giving examples of such situations: collecting data gathered through interviews and observations, taking of biological fluid without invasive act (saliva, urine, smear), taking of a small additional tissue or blood sample during an intervention needed for treatment purposes. The need to balance ethical considerations of risks and possible harms for persons without the capacity to consent with the potential benefits of research for these persons is also

emphasized in the recent report of the IBC on consent. It should be taken into account that it is

> … not acceptable to abandon … groups of people who lack the ability to make their own choices to the suffering and consequences of diseases and conditions peculiar to them. Research into paediatric illness and child development, schizophrenia, degenerative neurological disease and so on is needed (IBC, 2007).

THE EVOLUTION OF THE ARTICLE

The IBC Drafting Group in its third meeting in July 2004 identified several general or fundamental principles and mentioned consent as one of the implications of such principles in the Second Outline of a Text (IBC, 2004a). The Third Outline provided a textual formulation for an article on (informed) consent. Part b of this draft refers to persons not capable of consent:

> When, in accordance with domestic law consistent with international human rights law, a person is incapable of giving consent, such consent [authorization] should be obtained from his/her legal representative, having regard to the best interest of the person concerned (IBC, 2004b)

The Fourth Outline, elaborated by the IBC Drafting Group in December 2004, however, expanded the article on informed consent, and in particular the relevant parts concerning persons without the capacity to consent. A distinction was made between research, on the one hand, and medical diagnosis and treatment, on the other:

> c) When in accordance with domestic law a person does not have the capacity to consent, a research may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may 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 intended to contribute to the health benefits of other persons in the same age category or with the same medical condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.

> d) When in accordance with domestic law a person is incapable of giving informed consent, authorization for medical diagnosis and treatment should be obtained in accordance with domestic law in the best interest of the person concerned (IBC, 2004c).

The Preliminary Draft Declaration, finalized and approved by the IBC in February 2005, reduced the wording of the draft article on informed consent and presented a more succinct version of the text which concerned persons without the capacity to consent. In the wording, any reference to possible procedures to obtain substitute consent was deleted:

> c) In any decision or practice involving persons who do not have the capacity to consent, special protection shall be given to such persons. Such protection shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration (IBC, 2005).

In the First Intergovernmental Meeting of Experts in April 2005, it was made clear that all experts considered the article on consent a key article of the Declaration. At the same time, comments were made concerning exceptions to the principle. Some representatives felt that in dealing with persons without capacity to consent, paragraph c (quoted above) was too limited and they also preferred an explicit reference to mentally disabled people. The need to include specific high standards for the protection of persons not able to consent was emphasized (Report expert meeting, 2005a).

During the Second session, the intergovernmental delegates reiterated the positions taken in the First session. Some delegates underlined that the provision concerning persons incapable of expressing their consent should be further developed (Report expert meeting, 2005b). The Chairperson of the meeting called for an informal group, co-ordinated by the representative of Italy. This group drafted in fact two separate articles on consent. The first article deals with the conditions required for consent in regard to, on the one hand, scientific research and, on the other hand, preventive, diagnostic and therapeutic medical intervention. The second article is devoted entirely to persons incapable of giving consent. The wording of this second article was approved by all delegates (as Article 7 of the draft declaration). The restrictive conditions under which research might be envisaged in such patients are those generally accepted in international ethical texts, for example the Convention on Human Rights and Biomedicine (Council of Europe, 1997), as well as in national legislation.

THE ISSUE OF PATERNALISM

Persons without the capacity to consent evidently have health needs as do others. A major issue for our subject, much debated in recent decades, is the one of paternalism, that is acting for others. This is based on the assumption that the person deciding has some adequate authority or should know better than the patient what is best for him or her. The principle of autonomy is now universally accepted (Article 5 of the Universal Declaration on Bioethics and Human Rights). In health care practice, it is a common observation that one is not confronted only to authoritarian forms of paternalism (by professionals or by persons close to the patient). The patient-carer relationship needs mutual trust and empathy, and this trust and empathy might lead the patient to ask that the professional decide the course of action to choose, to the best of his or her knowledge. Some benevolent paternalism takes place in real life and, in our opinion, is not necessarily misguided or exerted against the patient's wishes. It is a matter of finding honestly the right balance considering a trusting human relationship, the wish to support and protect a comparatively fragile individual, and the ethical and legal rules.

CAPACITY

With this term one refers to the ability to understand a given situation and the issues involved in the decision and to evaluate them (*cognitive dimension* of capacity), the ability to make a rational decision, and the ability – and freedom, as the case may be – to act effectively to implement the decision (*volitive dimension*).

Capacity is used in two senses of importance for our subject:

a. In the *legal sense*, it refers to the capacity to validly bind or commit oneself toward others, for example in contracting marriage, in buying and selling real property. Laws (Civil Code) fix the age of majority at which everyone benefits from this right. The law however – or possibly the jurisprudence or prevailing juridical doctrine – might specify that so-called *strictly personal rights* can be exercised autonomously by legal minors (see below).
b. The other meaning can be called *medico-ethical* (or psychosocial), which Cassiers (2001) calls *de facto* capacity – a notion which may vary from one society to the other: it is accepted that, though they have not reached civil majority, teenagers may exercise the right to request, accept or refuse health care. The same is true for all persons under guardianship.

> A first distinction must be made between *de facto* incapacity and *de jure* incapacity. Patients falling suddenly in a state of confusion or coma haven't lost their legal capacity but are de facto incapable. Conversely, legally minor children, adults under guardianship or persons with severe mental conditions do not enjoy, in part or altogether, legal capacity but are not necessarily incapable to judge of their health (…) Without ignoring possible legal difficulties, one can say that the generally accepted ethical position considers that the physician must base his action on the *de facto* capacity in everything regarding diagnosis and treatment. He is thus not exempted, for example, to try as best as he can to inform children, handicapped persons or mental patients in order to obtain from them the best possible consent. Though progress has been made in this respect, physicians still ask too often the opinion of parents or legal guardians without taking enough care to enlist the participation of the persons directly interested (Cassiers, 2001: 511–512).

The United Nations Convention on the Rights of the Child (1989) asserts that children have the right to say what they think should happen when adults make decisions that affect them and to have their opinion taken into account (Article 12), have the right to get and share information (Article 13), and have the right to privacy (Article 16). All these assume growing levels of capacity to consent, which have to be taken seriously.

Legally, reaching the age of majority is the sufficient condition to exercise one's capacity (barring conditions which make it necessary to provide the person with a guardian or appoint a ward). In the medico-ethical sense, while chronological age is not determining, deciding upon the capacity to consent is a matter of appreciation.

In certain legal systems, the capacity to consent in health care issues is the same as that in civil or civic life (the capacity to commit oneself or the right to vote). Up to the age of majority, children and youth need their parents or legal representatives' consent. This is also in relation with culture and customs: in certain societies, the head of the family or of the group is traditionally consulted – or decides – about health care for members of the family or group. Such practices pose questions in respect to the autonomy of individuals.

In countries such as Switzerland the right to request, accept or refuse health care is considered a strictly personal right that persons capable of (sound) judgment, even if legally minors or incapacitated adults (under

guardianship) can exercise autonomously (for example, Article 19, para. 2, of the Swiss Civil Code); this even without the assent of their parents or without them being informed. This is an important feature in the daily life of health professionals and services: for example when a teenage girl asks for contraception, termination of pregnancy, or simply requests her physician to observe strict confidentiality towards her parents. In a word, those persons who are minors but capable of judgement are to be considered as legal adults in their relationship with the health system.

ASSESSING CAPACITY OF JUDGMENT

The general legal rule to be kept in mind is that capacity of (sound) judgment is assumed in adults: it is the incapacity that has to be demonstrated; in other words, proof of incapacity is required, not proof of capacity.

In the case of teenagers or persons under guardianship, assessing whether they are capable of judgement regarding health care is not defined by law, but is a matter of appreciation (evaluation, judgment) by the professional(s). This appreciation depends on the circumstances of the request for care (the professional would judge differently a demand by a teenage girl for the treatment of a wart, for the contraceptive pill, or for sterilization). With adults under guardianship, one shall make a comparable evaluation, taking into account the specificity and severity of the circumstances and of the related decisions. As the IBC stated in its recent report on consent:

> Clearly, some decisions are easier to make than others insofar as they are more readily understood and the consequences of a poor choice are less onerous or dangerous. One might properly apply some higher test of competence for decisions of greater moment. But here is important to be cautious because it may undermine the right of mature children to make their own decisions by setting the standards of maturity unacceptably high (IBC, 2007).

In the already mentioned Message to Parliament, the Swiss Government says:

> In research with human subjects, the requirements applicable to intellectual capacity, and especially to capacity of judgement (*capacité de discernement*), depend particularly on the seriousness of the prejudices or damages within the project as well as on the risks and constraints associated with it. The more the risks and constraints for the research

subject are high, the more the capacity of judgment has to be subjected to strict conditions (Switzerland, 2007).

REPRESENTATION AND SUBSTITUTE DECISION-MAKING

The above shows how important it is to set conditions that best respect the personality, dignity and interests of incapable persons. This is done:

- by having representatives entitled to give proxy consent,
- by setting conditions or limits on the type of research which might be undertaken.

As regards representatives, two main situations are to be considered:

Long-term, respectively permanent, incapacity

This is the case of small children, or persons with mental handicaps, learning difficulties or conditions altering severely their intellectual abilities and interpersonal relationships, for example Alzheimer's disease. The legal representatives of children are their parent(s) or designated guardian(s). Those of adult impaired persons are their guardians. The situation being chronic, and as compared with temporary incapacity, it is unusual that the physician (or health team) has to take on him/herself (or itself) to decide.

Temporary incapacity

These are situations of coma or confused condition – due to accident, acute disease, and surgical intervention – after which it is likely that the person shall recover full capacity to consent. In such cases, decisions about treatment must be guided by the best interest of the patient, as per the information received earlier from the patient about his/her history, interests and preferences, and from family and close ones.

Especially important in such case is the notion of *presumed consent*: one may assume that acting in the best interest of the patient as one can 'construct' it from the information gathered, he/she would consent. In a way, doing so presumes what his/her advance directives would be, if he/she had drafted some. As different from the chronic situation, it is often here the physician – in consultation with the caring team and if possible the patient's close ones – who has to make the decision (in cases of temporary incapacity of adults, it is frequent that there is no person formally entitled to substitute decision-making).

THERAPEUTIC REPRESENTATION

Legal texts are promulgated in a growing number of jurisdictions whereby capable adults (i.e. not already having a legal representative) might designate beforehand a therapeutic representative, entrusting him or her with the mission to decide for them in the case that they are no longer capable of doing so. This can be done in view of a possible accident or severe acute disease. All the same, it can be done in situations of progressive debilitating long-term disease, without likelihood of recovery – such as Alzheimer or other neurodegenerative disease like amyotrophic lateral sclerosis (ALS) – the understanding being that the designation should be done by the person while still competent. The designation of a therapeutic representative might be seen as the simplest form of advance directive.

ADVANCE DIRECTIVES

This is a relatively new 'instrument'. While they are capable of judgment, persons might let others know, through formal dispositions, the types of care they want to be observed in the case they later become, temporarily or permanently, incapable of consenting for themselves. This may relate to the acceptance or the refusal of particular types of care (e.g. intensive care, use of certain drugs, refusal of blood transfusion, certain psychiatric care, willingness to donate one's organs). Forms to be filled out are generally offered by professional bodies or lay associations. In principle, they are not subjected to formal conditions as long as the will of the persons concerned is clearly expressed and made known (they could be oral as well).

One aspect which differs from one country to the other is the binding character (for the caring team) of advance directives. In Switzerland, for example, laws of several cantons prescribe that health professionals have to follow them unless there are strong reasons to believe that the person had not envisaged the current situation, or if the directives are old and appear currently questionable. In other countries, there is a strong opinion that professionals should remain free to follow them or not, showing a reluctance to give directives a binding force. The fear is that those directives might interfere with deontological duties of the professionals, but it is clear that this attitude corresponds to a significant limitation of the autonomy of the patient in deciding on his/her health care.

REFUSAL – AN IMPORTANT RULE AND ITS DIFFICULTIES

As Article 7 says, under (a), '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'. This is a principle that has to receive a lot of attention from care providers, relatives and designated representatives.

However, it also raises difficult questions. For example, adverse manifestations are common in small children, when immunization or another injection is given, or an anaesthesia initiated for a required operation. Rarely should they lead to a renunciation of the foreseen care. The above-mentioned Message of the Swiss Government (Switzerland, 2007) says in this respect:

> According to the Convention on Biomedicine of the Council of Europe, an incapable person may validly refuse to participate in a research project. In case of refusal, the requirements in terms of intellectual capacity or capacity of judgment are less strict than for consent to participate in the same project. This does not mean however that the smallest exterior sign of opposition, such as a gesture with the hand or weeping, if they are an expression of a general worry about the 'white coat' of health professionals, should be considered as refusal (Switzerland, 2007).

Further, a noteworthy indication adds:

> The more the non-participation in a project would have serious consequences for the person, the more the capacity of judgment is to be subjected to strict requirements. The person must be able to take into account the direct benefits she would probably lose in not participating, if for example the best possible treatment for a severe disease is proposed only within clinical trials (Switzerland, 2007).

But the weight that has to be given to behaviour indicating opposition grows with the age of the patient, and in principle should not be discounted in teenagers deemed capable of giving free and autonomous consent.

Similar considerations are in order for mentally ill or impaired persons whose behaviour opposes care. As with children, the consideration of their whole situation (history, circumstances, previous care) and of the indispensable – or not – character of the treatment should guide the care team in adopting measures preserving best the health as well as the integrity and dignity of the patient.

RESEARCH INVOLVING PERSONS WITHOUT THE CAPACITY TO CONSENT

Section (b) of Article 7 summarizes in a few sentences the major conditions to be observed regarding research.

A key ethical principle is that studies should not be conducted with persons not able to consent, which could be undertaken with scientific validity on persons who can provide their own informed and free consent. Thus research with incapable persons could be carried out only when a direct benefit is likely for them. With the exception that research without direct benefit might be considered if there is no alternative of comparable effectiveness with participants able to consent. The possible risks linked to the research should always be as limited as possible and be considered in relation to the severity of the patient's condition and to the chances of a significant improvement. Desperate situations allow riskier procedures than research about pathologies that do not represent a threat to life or to major functions.

The right to stop participating in the research project is guaranteed, unless such withdrawal would result in an undesirable outcome to the volunteer; such a situation should be discussed beforehand between the professionals and the person concerned.

One should refrain from using vulnerable persons in research, except when the project is likely to bring them direct benefit or when no comparable study can be undertaken (i.e. relevant results obtained) with other patients (see Chapter 10 on Article 8 in this volume).

RESEARCH WITH CHILDREN

While the first imperative is to protect children, as with other persons unable to consent, from being used in an unacceptable manner, concerns have been raised in recent times that this restraint might not have always been in the best interests of such 'protected' groups; which may include minorities, women (especially pregnant women), and others.

Regarding children, there is evidence that the size of the investments required in order to present a new drug for licensing to the competent authorities has resulted in a trend that new medicines are not licensed for paediatric use but are, nevertheless, often used *off-label*, or even *off-license* under the guise of research protocols. This is a questionable practice. This can have detrimental consequences in terms of access to the most up-to-date treatments. The same may hold true for members of other groups such as minorities and women, for example in the sense that industry would not

undertake studies on diseases which might be more prevalent in those groups because of restraints on their involvement in research.

During 2007, the Swiss National Advisory Commission on Biomedical Ethics worked on this issue (SNACE, 2007); some of the theses it drafted are as follows:

- There is a definite, documented need for research involving children.
- Research with children includes pharmacological and interventional studies, as well as research about pedagogical, psychological and other questions.
- As compared with research with adults, research involving children represents specific problems.
- When involving children, the distinction between research with direct benefits for the participants and research benefiting others is especially important.
- The ethical legitimacy of research involving children depends on the welfare and interests of the individual child concerned.
- *Prima facie*, one may assume that the welfare, respectively the interests of the child, are best represented by his parents.
- Research is only allowed within the limits of a tolerable risk, to be defined (see also Kodish, 2005).

This last issue, 'tolerable risk', is a difficult one. It has been proposed to use comparisons with the risks of normal daily life (in playgrounds, in sports, in traffic), but this appears questionable. Risks taken by children as they 'live their lives' appear to us to be accepted in quite a different way than risks incurred when consenting to take part in medical research.

CONCLUSION

Obtaining consent for decisions to be made about health care or research involving persons without the capacity to consent is a particularly delicate theme in medical ethics and bioethics. One has to consider both legal civil (*de jure*) capacity and *de facto* capacity in a medico-ethical sense. Law or juridical doctrine might declare that legal minors (teenagers, some persons under guardianship) have the 'strictly personal right' to autonomously request, accept or refuse health care.

Modern bioethics gives weight to the *de facto* capacity. Translation into practice may depend on national or local legislations as well as on culture. In any case, the paramount rule remains to respect fully the dignity of the person, no matter what deficiencies he or she may have, and to be as close

as possible to the situation prevailing with competent adults; that is to take maximum advantage of the person's potential contribution to the decision to be made, be it to consent or to refuse.

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Chapter 10

ARTICLE 8: **RESPECT FOR HUMAN VULNERABILITY AND PERSONAL INTEGRITY**

Maria Patrão Neves

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.

BACKGROUND

Article 8 is included in the section dealing with the principles that should be observed in all the decisions and practices in the scope of the present Declaration and states the obligation of 'respect for human vulnerability and personal integrity'. This article was one of the two that were never part of the successive preliminary projects drawn up by the IBC. It was proposed and accepted during the second and final Intergovernmental Meeting of Experts aimed at finalizing a draft Declaration on Universal Norms on Bioethics, in June 2005 (Report expert meeting, 2005).

This principle draws attention to two different realities – human vulnerability and personal integrity – that are inter-related and both fundamental in the field of bioethical reflection and practice. Frequently considered to be ambiguous in meaning and vaguely defined, these expressions need to be explained separately.

The notion of 'vulnerability'

'Vulnerability' is a term of Latin origin, derived from *vulnus* which means 'wound'. 'Vulnerability' is then defined as the susceptibility of being wounded.

This etymological-conceptual meaning is the most common one, used in everyday language, and is also the one that arose within the field of bioethics, in 1978, in the *Belmont Report: ethical principles and guidelines for*

the protection of human subjects of research. Vulnerability is here applied both to individuals, in the section on 'voluntariness', and to populations, in the section on 'the systematic assessment of risks and benefits'. Addressing the topic of 'informed consent', the report specifies some vulnerable populations and underlines the respective need for protection, under the heading of 'Selection of subjects':

> One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition (National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979).

Actually, the notion of 'vulnerability' was introduced into the vocabulary of bioethics in the ambit of human experimentation, as a characteristic attributed to particular populations considered, for different reasons, as those most exposed to and poorly defended against the maltreatment and abuse of others. Indeed, historical factors were decisive for the generalization of this characteristic, which is still predominant: human experimentation developed on an ever growing scale throughout the first half of the twentieth century, involving unprotected and/or institutionalized groups of persons like orphans, prisoners, the elderly and, later, Jews and other ethnic groups, considered as inferior and even subhuman by the Nazis, or persons such as the Chinese, who were exploited by the Japanese in order to pursue their scientific and military objectives.

These groups came to be classified as vulnerable. Later, ethnic minorities, socially underprivileged groups and women were added. The description of these groups as vulnerable implies the obligation to defend and protect them, so that they will not be 'wounded' or ill-treated. Bioethics has attempted to justify this, mainly by reinforcing the principle of autonomy and of the consequent demand, increasingly more inclusive and stricter, for informed consent. The principle of autonomy is viewed not merely as the recognition of the capacity common to all persons 'to hold views, to make choices, and to take actions based on personal values and beliefs', but also as the effective

creation of conditions 'enabling a person to act autonomously' (Beauchamp and Childress, 2001: 63). In this sense one can say that vulnerability, held as a provisional and contingent quality of persons and populations to be protected, should be overcome by the reinforcement of their respective autonomy, brought about by the additional demand for informed consent, or rather, to use a more currently acceptable term, by their empowerment.

This has been the predominant meaning of the notion of vulnerability, not only in the distant past referred to above, but also at present, as can be verified in the 1996 revision of the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. Article 8 refers to vulnerability attributing it to some 'populations subject to investigation' for whom 'special protection' is required:

> Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care (World Medical Association, 2004: Article 8).

The first UNESCO declaration on the subject of biomedicine, the Universal Declaration on the Human Genome and Human Rights, of 1997, also refers in Articles 17 and 24 to 'vulnerable groups', individuals and families, as deserving special attention. The International Ethical Guidelines for Biomedical Research Involving Human Subjects, of the Council for International Organizations of Medical Sciences (CIOMS), in its third and most complete version of 2002, makes extensive reference to vulnerability which is always used adjectivally to describe "'classes of individuals', subjects, persons, groups, populations, communities, defining 'vulnerability' as 'a substantial incapacity to protect one's own interests'" (CIOMS/WHO, 2002).

More recently, departing from the development of bioethics in continental Europe, which began in the 1980s, the notion of vulnerability, still corroborating its etymological sense, gained a new, broader meaning, arising from the reflection that philosophers like Emmanuel Levinas and Hans Jonas had begun to dedicate to it.

Levinas was the first to treat vulnerability as a philosophical theme, in his work *Humanisme de l'autre homme* (1972), where he defines it as 'subjectivity'.

In accordance with Levinas' view of subjectivity, the self always comes after otherness. Thus, when the 'self', the subject, arrives, s/he is already in relation to the other, who waits for her/him, who makes her/him be. Therefore, the self is in dependence to the other and hence vulnerable:

> The Self, from head to feet, until the bone marrow, is vulnerability. (« Le Moi, de pied en cap, jusqu'à la moelle des os, est vulnérabilité ») (Levinas, 1972: 104).

Thus 'vulnerability' enters the vocabulary of philosophy as an intrinsic state of the human, the universal condition of humanity, in so far as the self only exists in relation to the other.

Hans Jonas, in *Das Prinzip Verantwortung* (1979), also draws attention to the relevance of the philosophical meaning of 'vulnerability', first, by specifying its meaning as a perishable characteristic of what exists; later, and in consequence, extending its reality to the whole of nature. Everything that exists, simply because it exists, is perishable and herein resides its vulnerability (Jonas, 1979). The human being is thus naturally and ontologically vulnerable.

Vulnerability is currently regarded as a human condition, inherent to existence in its radical finitude and fragility, so that it cannot be eliminated or surpassed. It requires the care of others, the responsibility and solidarity of others in the recognition and non-exploitation of that condition. It is in this sense that vulnerability comes to constitute a theme for development in bioethics and also a principle to be respected, just as it is presented for the first time, in 1998, in the Barcelona Declaration, in its classification of four fundamental principles for a joint European policy in the field of bioethics and biolaw:

> Vulnerability expresses two basic ideas. (a) It expresses the finitude and fragility of life which, in those capable of autonomy, grounds the possibility and necessity for all morality. (b) Vulnerability is the object of a moral principle requiring care for the vulnerable. The vulnerable are those whose autonomy or dignity or integrity is capable of being threatened (*Barcelona Declaration,* 1998).

There are substantial differences between the circumstantial Anglo-American bioethical references to vulnerability and its European treatment as a theme in bioethics, even though they articulate perfectly well: from its adjectival function, qualifying certain groups and persons, vulnerability comes to be used as a noun, describing a reality common to human beings; from a contingent and temporary characteristic, it becomes a universal, indelible condition; from a factor of differentiation (if not one of discrimination – according to some

commentators) between populations and individuals, it becomes an equalizing factor amongst everyone; from privileged consideration in the field of human experimentation, it gains constant attention in the area of clinical assistance and health care policies; from demanding autonomy and the practice of informed consent, it comes to demand responsibility and solidarity.

In fact, in the present world of bioethics, the notion of vulnerability encompasses both meanings: the first, narrower, adjectival sense, commonly and immediately comprehensible; the second, as a noun, broader in meaning and referring to an anthropological perspective, as the foundation of ethics. Both of these meanings are implied in the allusion to vulnerability in Article 8: 'human vulnerability should be taken into account' as an inherent feature of the human condition, seen in its irreducible finitude and fragility as a permanent susceptibility to being 'wounded' that, as such, can never be suppressed; and 'individuals and groups of special vulnerability should be protected' whenever that inherent human vulnerability is aggravated by particular circumstances.

The notion of 'integrity'

The term 'integrity' is also of Latin origin. It is derived from the verb *tangere* which means 'to touch', to 'hit'. This is the root both of the adjective *integer,* which means 'untouched', 'integral', and the noun *integritas* which means 'totality', 'integrity'. The noun 'integrity' evokes both the state in which all the parts are maintained and the quality of that which is unaltered, also functioning then as an adjective.

It was precisely with the latter sense of 'the quality of that which is unaltered' that 'integrity' entered the vocabulary of bioethics and the sense that has been maintained in its most common usage. This was confirmed in 1996, in the Declaration of Helsinki, in which the noun 'integrity' is used in the 'Basic Principles' section as an attribute of the recognized inviolability of the subject of experimentation, which should not be 'touched' physically or psychologically:

> The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject (World Medical Association, 1996: I.6).

It is with this sense of 'not touching', 'keeping intact', or 'not affecting physically or psychologically' that the Convention of Human Rights and Biomedicine alludes to integrity in its first article:

> Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine (Council of Europe, 1997).

At this biomedical level of meaning, 'integrity' is presented as a right to which all persons are entitled, a negative right or a right of non-interference which, as such, demands respect from the others, that is, non-interference of the others in the private sphere of the self.

Similarly, 'integrity' is presented as a virtue, or disposition to act in a certain way, attributed to all those who remain unalterable, incorruptible, particularly by outside influences or pressures. This is the common deontological sense that is found in the two earlier UNESCO declarations: both Article 13 of the Universal Declaration on the Human Genome and Human Rights (1997) and Article 15 of the International Declaration on Human Genetic Data (2003) refer to 'integrity' as a responsibility or virtue that the investigator should develop and society should demand.

Nevertheless, and once again in the wake of the development of bioethics in continental Europe, mainly in its philosophical foundation in a humanist tradition, the meaning of 'integrity' as 'totality' is reiterated.

One could refer to various philosophers, from Maurice Merleau-Ponty, and his conception of a 'lived body', to Paul Ricoeur and his conception of personal identity as 'narrative identity'. Merleau-Ponty, mainly in *Phénoménologie de la perception* (1945), surpasses the traditional, anthropological duality, showing that man is not a sum of the parts, the body and the mind, but rather its inseparable unity, a lived body and an incarnate subjectivity. The multidimensional character of the individual is clearly assumed today in the understanding that his/her physical, psychological, social, intellectual and spiritual dimensions cannot be separated or abstracted without loss of the totality that the individual comprises. Ricoeur (1988) proceeds to a hermeneutics of the subject, and states that the narrative that each individual creates about itself, in a fusion of history and fiction, unifies the events of a life and the transformations of a subjectivity in the course of its historicity, allowing him/her to construct his/her personal identity. Today it is understood that that singular identity is not restricted to a present reality, but is integrated in the history of a life, from past experiences to future fears or expectations, in which the different events are articulated and gain a significance of their own.

'Integrity' is now seen as the totality or oneness that each person comprises, in the plurality of his/her dimensions and throughout his/her existence, as the coherence of a life. Hence a reality which, once again, appeals to the care of others, so that it is never 'touched' or broken up. It is, above all, with this third and final sense that 'integrity' gains prominence in the field of bioethics, although frequently associated with the two former meanings referred to above. The Barcelona Declaration (1998), which includes 'integrity' amongst the four basic principles of bioethics and bio-law, shows the fuller, plural sense that the noun can acquire by defining it as the 'untouchable core' of the person which 'must not be subject to external intervention' as it refers to the 'coherence of life of beings with dignity that should not be touched and destroyed'.

EXPLANATION OF THE ARTICLE

This broader sense of 'integrity', implied in the allusion to the concept in Article 8 of the Universal Declaration on Bioethics and Human Rights through its qualification '*the personal integrity*', is dissipated in so far as the expression refers only to '*such individuals*', those with added vulnerability. The initial proposal that 'human vulnerability and personal integrity should be respected' was not understood in the full sense that 'integrity' expresses, but rather was interpreted in its restricted sense by most of the experts at the meeting in June 2005 and thus applied only to the most vulnerable – an interpretation that remained unaltered until the approval of the final version of the article. So, to sum up, the principle of '*respect for human vulnerability and personal integrity*' first states the obligation of taking into consideration the vulnerability inherent to all human beings. That is to say, it is important to gain awareness of the fact that a person is vulnerable, is exposed to being 'touched' by the other, subject to diverse and often subtle forms of exploitation or abuse, irrespective of his/her level of autonomy. Secondly, it gives priority to individuals and groups classified as vulnerable, for whom it demands not only protection against being 'wounded' but also respect for their integrity, so that they are not reduced to merely a part of themselves and so considered abstractly.

It is this double meaning that justifies that Article 8 is introduced after the principle of 'Consent' (Article 6) and immediately following 'Persons without the capacity to consent' (Article 7), insomuch as it responds to all the situations that offend the dignity of the person and are not preventable by these two articles, that is, situations in relation to which the principles of autonomy and consent prove insufficient. Indeed, the principle of '*respect for human vulnerability and personal integrity*' should preferably be linked to that

of 'human dignity', which reinforces the statement of the unconditioned value of the human beings by demanding his inviolability.

In this context, and as a result of the initial criticism that 'vulnerability' and 'integrity' are ambiguous concepts (Danis and Patrick, 2002; Morawa, 2003), it follows that they are not clearly of a normative nature; therefore, they fail to be widely recognized of their status as principles, and, consequently, of the expression of any obligation of action. In fact both concepts lie on a descriptive level of human reality – onto-anthropological – but, because they are not axiologically neutral, they simultaneously express a prescriptive meaning, whose norm is contained in the term itself: 'vulnerability' and 'integrity' should be recognized as intrinsically human dimensions, components of personal identity which, as such, deserve to be respected, that it to say, taken into consideration at the various levels of human activity.

APPLICATION OF THE PRINCIPLE

The principle expressed in Article 8 intervenes in a pertinent and indispensable manner at the three levels in which bioethics has developed: human experimentation and biomedical research, clinical practice, and health policies. The principle of vulnerability requires the recognition that the exercising of autonomy and the giving of consent do not eliminate vulnerability which, subtly and surreptitiously, is still susceptible to exploitation, for example through optimistic presentation of clinical trials, for whom volunteers are needed, or the compensation offered to them, such as free medical examinations and clinical assistance, or by the exaggeration of biomedical successes in the media. The latter situation creates unrealistic expectations in patients and in society in general, in which the process of medicalization is being aggravated. Thus people turn to biomedicine as the solution to all human problems, placing unbearable pressure upon it, whilst discouraging alternative means to a solution; an infertile couple may resort to reproductive technology, but may also refuse to be submitted to infertility treatment and accept infertility as a condition of their life. Within the field of clinical assistance, the principle of vulnerability helps to reinforce the rights of patients. At the same time, it appeals to the responsibility of the health professional in establishing symmetrical relationships with the patient and forces institutions to protect citizens even when they make no complaint. The needs and interests of patients or groups of patients with less power to revindicate should not be underestimated, which means that the excesses of patient lobbies can be counteracted. In the field of health policies, the principle of vulnerability demands, both at the social and international level, that the

benefit of some should not be attained by exploiting the weakness of others, as well as the understanding that the greater wellbeing of only some will make the rest, the excluded, even more vulnerable. Hence national policies and also those of bio-industries must not aggravate human vulnerability but rather seek to eliminate it as far as possible and to respect what is beyond their reach.

The principle of respect for human vulnerability and personal integrity demands a new conception of the human body and disease: a body is no longer an object but a subject and hence inseparable from the person it comprises; a disease is not a purely objective phenomenon but only gains reality in a lived body and significance in the history of a life. At the level of experimentation it demands protection which goes beyond that which can be expressed in informed consent and which refers to the prohibition of the objectification of the body or part of the body and demands respect for personal identity in the relationship between the subject of experimentation and the researcher, and also between patient and doctor, at the level of clinical assistance. Here, respect for integrity demands new forms of communication that permit the doctor to focus more on the patient than the illness, which then facilitates the involvement of the patient in his own therapeutic process as a partner in the health team, and, consequently, the development of therapies which are perceived as less invasive and more respectful of the individual, for example, at a cultural or religious level. In the field of health policies, the principle can play an important role in the prohibition of commercializing human body parts, in the regulation of genetic manipulation, particularly in safeguarding the human genome, and in the consideration of patentable human matter.

In short, the principle of respect for human vulnerability and personal integrity inaugurates a new logic in ethical reasoning which no longer implies the claim of persons' rights but the solicitude of obligations that are due to all: the complementarity between a consolidated ethics of rights, based on the freedom of the individual and developed by reinforcing autonomy, and a pressing ethics of duties, based on the responsibility for the other and developed by reinforcing solidarity.

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Chapter 11

ARTICLE 9: **PRIVACY AND CONFIDENTIALITY**

Jeanine-Anne Stiennon

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.

DEVELOPMENT AND CONTENT OF THE ARTICLE

The very title of the article stresses the relationship between privacy, confidentiality and consent before revealing information concerning persons. Respecting the autonomy of the person means that for his or her consent clear, exact and sufficient information is required.

The basic principles and values of Article 9 emerge from the Universal Declaration of Human Rights of 1948 and other subsequent declarations and international conventions. It has to be noted that the notion of confidentiality is found already in the Hippocratic Oath. The dignity and autonomy of the person, being an integral part of rights and fundamental freedom of human beings, has to be recognized and respected in an effective and universal manner.

In this general context, cultural and psycho-social factors of persons and social groups have to be considered. Particular and precise arrangements, on a legal and social framework, have to be anticipated for persons and vulnerable populations and communities that are unable to formulate their consent and this group of people should have the opportunity to be treated in a just and fair manner.

At the initiative and under the aegis of the International Bioethics Committee of UNESCO, the Universal Declaration on Bioethics and Human Rights was elaborated and finally proposed as a Preliminary Draft

Declaration to the two intergovernmental expert meetings on April and June 2005. Multiple axiological and normative principles and values are strongly stated and they do not have a hierarchical, univocal and frozen command. The interdependence, complementarities and related nature of the principles is explicitly stated.

Article 9 on confidentiality and respect of privacy of the person has since the beginning relied on articles related to autonomy and consent. In the explanatory memorandum of April 2005 the IBC clearly stated the content of the article (UNESCO, 2005).

1. A right to privacy guarantees a control over personal information in many ways. It restricts access to personal and medical information and it provides a claim of non-interference in various private spheres of the individual. Privacy extends beyond data protection, as certain private spheres of the individual that are not manifested in data processing can also be protected by the right to privacy.
2. Confidentiality refers to a special and often fiduciary relationship, such as that between researcher and research subject, or doctor and patient, and provides that the shared information shall remain secret, confidential and shall not be disclosed to third persons, unless a strictly defined, compelling interest justifies disclosure under domestic law.
3. The importance of privacy has been recognized in numerous legal instruments, such as the OECD Guideline on the Protection of Privacy and Transborder Flows of Personal Data adopted in 1980 (OECD, 1980); the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data; and the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data.

The draft version of Article 9 was transmitted by the IBC in April 2005 and was discussed only during the second meeting of intergovernmental experts in June 2005. The debate was essentially centered on exceptions related to privacy and confidentiality where specific legislation exists in certain states. The text was adopted by means of a paragraph specifying that the Declaration has to be understood in a coherent manner under international and national law, and conformed to international law of human rights (Report expert meeting, 2005).

In order to respect the prerogatives of States, some imperative formulations of principles in the Declaration elaborated by the IBC have been rewritten into optative recommendation form such as the word 'must' has been replaced by 'should be'.

MEANING OF THE ARTICLE

The evolution of scientific discoveries, their technological applications and the explosion of communication and information techniques have upset the relationship among patients, practitioners, scientific bodies, techniques, trade, industrialists and the State. In this extremely complex and ever shifting context, Article 9 restates the bioethics principles of confidentiality so that scientific, technical and operational innovations lie within the framework of respect of human dignity, autonomy and fundamental freedom of the human being. Recognizing the importance of progress made in biosciences and medicine, the article adds privacy and confidentiality within international law that regulates the diffusion and utilization of the ever increasing, precise, mobile, exploitable and manipulable personal data.

In practice, the rights and freedom of individuals are in conflict with the exigencies of the 'common good' and with the potentialities of information technology. The confidentiality of medical data is confronted with a set of legal and factual situations that could limit its scope. Examples are: Screening of pathogenic agents or diseases, genetic or immunological typing, identification of potential offenders, codes of public health, interdependent social situation (social services, social insurance, preventive medicine, hygiene, and psychiatry). The interests of certain economic sectors linked to the exploitation of data such as therapy and/or marketing are also involved. The Article reminds all (operators, decision-makers, individual or collective users, or public responsible party) about the pressing necessity to take into consideration individual duty towards confidentiality and privacy. It invites the national and international lawmaker to acquire the tools for appropriate governance. It calls on practitioners, researchers and experimenters within the medical and pharmaceutical disciplines to respect the autonomy of human beings who are their operational area.

In the perspective of the increasing dematerialization of individuals, places and objects that are progressively transformed into microchips that supply the cyberspace, this principle recalls that human beings have a fundamental right to confidentiality of their data and to free consent prior to the utilization of their data.

In conclusion, the principles of respect of privacy and confidentiality as well as consent are cross-cutting many fields and issues in bioethics. The issues refer to rights of patients, utilization of constituents and products of the human body, human experimentation, assisted reproduction, genetic test and data, bio-banks and marketing prospects worldwide.

All those areas are regulated by a 'biolaw' that is constructed in a progressive way and that has to play the role of marker and guarantor in the vast and complex field of future bioethics. Even if not specifically related to bioethics, a vast number of national, regional and international official texts are concerned with human rights in bioethics (Delfosse and Bert, 2005). It has to be noted that a guide referring to confidentiality and respect of privacy, intended for health professionals has been elaborated by EUROSOCAP (2006).

It is appropriate to recognize that, in the framework of the right to self-determination of private information, the protection of privacy has to be balanced by the collective health and social exigencies, security and fundamental rights of the patient (as expressed in Article 27).

Medical secrets can therefore be exempted, and under some circumstances the rule may be set aside or even violated under particular legal frameworks. This is, for example, the case for health insurance, regulations of health institutions, security at work and the protection of minors.

Scientific and technical development has resulted in the need to accommodate the imprescriptible duty of confidentiality. Indeed, confidentiality is complicated by the fact that the flow of information is in the very interest of the patient. New confidentiality problems have also arisen from the computerisation of health administration.

In the context of management of health problems and the prevention of diseases, government can intervene in the confidentiality domain. Conflict may arise between just and equitable treatment in the social context and an individual's right to privacy.

In a complex and evolving context, confidentiality regarding personal data is a major ethical challenge.

APPLICATION AND CASE STUDY

The potential utility of Article 9 is therefore significant in the current bioethics debate in an institutional and legal context, as well as on a practical and functional scale.

Research in pharmacogenetics and subsequent clinical trials of medications for human consumption illustrate a current application of Article 9. Following a request from hospital ethics committees to include pharmacogenetics in experimental protocols, the Consultative Bioethics Committee of Belgium on 15 December 2003 published a notice (Comité Consultatif de Bioéthique de Belgique, 2003).

The Consultative Committee is aware of the importance of this field of research. Genetic analysis during clinical trials for the development of new medications might identify susceptible patients (responders) among others that have a lower probability of expected response (non-responders). It might also be possible to identify subjects particularly susceptible to secondary effects (adverse responders). Eventually, pharmacogenetics might enable the prescription of individualized therapy. Currently, its application is still in the research field but widespread future utilization does not present major technological challenges. However, it raises major ethical, social and legal issues.

Methods of sampling, conservation and identification have important ethical considerations. The researcher, the instigator, public authorities and ethics committees should have the same understanding of terminologies such as anonymous, rendering anonymous and encryption. Even after rendering anonymous or encrypted, data related to samples might still be associated to the ethnic or geographical origin, socio-economic level and the lifestyles of specific populations, thus stressing the importance of the nature of information attached to samples.

In its comment, the Committee has deemed it important to discuss three principal ethical issues:

1. Can an instigator impose part of a protocol and make it a *sine qua non* condition for an institution to participate in a clinical trial before any advice is provided by the Ethics Committee?
2. Are ethical issues of blood sampling for a pharmacogenetic study different from those posed when a classic sample is taken, e.g. to detect an eventual toxic effect?
3. What recommendations should be formulated to ethics committees, researchers and authorities? What prior information should a normal or ill volunteer prepare before participating in a study?

The Consultative Committee considers that genetic data should be processed while respecting strict confidentiality. It further states that the data will remain associated to an identifiable person as long as this identification is a necessity to attain the research objective and under the condition that the protocol

comprises of all precautions preventing the identity to be revealed except to the researchers involved. While collecting samples or data, researchers should make sure that procedures described in the protocol are respected.

After rendering anonymous or encryption, utilization of the data will be strictly limited to the agreed protocol. The utilization of a sample for other means than that defined by the protocol requires a new consent if the sample is identifiable, except if the patient has previously agreed to all research. The sample would be destroyed at the end of any research activity.

Finally, according to the European Directive 2001/20/CE of the European Union, local authorities will verify that the procedures follow protocols and will ensure the legal follow-up of collected data. Authorities would also detail the rights and duties of every actor involved in human experimentation.

In this respect, the Consultative Committee of Bioethics of Belgium recommends that the diverse issues raised by the administration of databanks should be managed at the European level.

In conclusion, this issue relative to current research in pharmacogenetics addresses not only a country or a region, but it is closely related to globalization. The autonomy of the person has to prevail by favouring integrity and transparency in the manipulation of data while avoiding a conflict of interest during the decision-making process. Internationally, the conditions of collaboration by negotiating equitably between concerned parties have to be detailed.

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Chapter 12

ARTICLE 10: **EQUALITY, JUSTICE AND EQUITY**

Gabriel d'Empaire

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.

BACKGROUND

More than 24 centuries ago, Aristotle has clearly stated the relevance of justice throughout human history:

> Justice sums up all virtues in itself ... Justice, then, in this sense of the word, is not a part of virtue, but the whole of it; and the injustice which is opposed to it is not a part of vice, but the whole of it (Aristotle, 2004: 99).

Even though many centuries have passed, the importance expressed by Aristotle when referring to this virtue remains accepted today. Justice has been identified as a perfect virtue and, unlike wisdom or charity, as a perfect duty. This establishes an important difference: Charity is an imperfect duty, it is a duty of beneficence, private and non-enforceable, while justice is a perfect duty, a right which could be enforced by law (Gracia, 1995). Justice has been understood throughout history to be a secular, rational, enforceable, and practicable virtue (Fleischacker, 2004). A person with a valid claim based on justice has a right, and therefore is due something.

The relevance of the principle of justice parallels the great complexity of its definition and application. Indeed, justice is a very complex term which includes different meanings. Aristotle described different forms of justice which are still used to some extent. General justice, considered by him as the 'complete virtue', is the canon or the framework of any normative ethics. Justice is giving to each person what is due to each. Or, once again according to Aristotle, it would be unjust '...When persons who are equal do not receive

equal shares, or when persons who are not equal receive equal shares' (Aristotle, 2004: 102). Different theories have described justice in different ways, but all of them define it as a formal canon (Gracia, 1997). This concept of justice is *formal*, it does not define what is due. It identifies no particular term in which equals ought to be treated equally and provides no criteria for determining whether two or more individuals are equals. Besides this formal concept, other concepts of justice have also been described. These are *material* or more specific concepts. Aristotle described corrective or commutative justice as the one regulating 'private transactions' and also, this kind of justice calls for wrongdoers to pay damage to their victims in accordance with the extent of the injury they have caused. Aristotle also described distributive justice which, according to its original description, establishes the 'distributions of fees, wealth, and the other things that are divided among the members of the body politic' (Aristotle, 2004: 101). In the former case, the victims of wrongdoing must be compensated equally, regardless of merits, in the latter everyone must be rewarded in proportion to his or her merits. Throughout history, the classic and formal concept of general justice as a formal canon has continued to be the same. However, in terms of distributive justice, an important change occurred. At first, throughout the passing of the centuries, medicine was considered private and accordingly based on commutative justice. The social revolution in the middle of nineteenth century introduced the concept of social medicine based on distributive justice. But in this case, a different concept of distributive justice than the one initially proposed by Aristotle was adopted (Fleischacker, 2004: 19). Distributive justice, in Aristotle's sense, considered the principles that should ensure that deserving persons were rewarded according to their merits, especially in regard to their political status. This concept of distributive justice prevailed until the modern era when it started to change. Distributive justice in its actual sense is based on how a society should allocate its resources among individuals with competing needs but without taking into account their merits. Today, it is commonly accepted that basic needs have to be awarded to everybody, not as a charity, but as a right based on justice.

Other material principles of distributive justice have been proposed, for instance: each person must receive an equal share, each person must receive according to his or her needs, each must receive according to his or her effort, or according to his or her contribution (Beauchamp and Childress, 2001).

Distributive justice becomes more important under conditions of scarcity, which clearly explains its actual importance, and justifies highlighting its meaning and applications in a world where a rapid development of

technology clearly contrasts with serious limitations for its fair uses. This contrast becomes more evident when a serious intention of achieving equality, equity, and justice is made in a time in which biotechnology should be taken into account in a scenario of scarce resources (Callahan, 2002). In this way, distributive justice has become one of the most important concepts in bioethics. Different theories of justice have been proposed in an attempt to create a framework to justify morally the distribution criteria; the liberal, the socialist, or the utilitarian theories are different forms of interpreting how the scarce resources must be distributed. However, none of them are accepted universally. Even when it has had some criticism, one of the most important theories is the one proposed by Rawls (1993). According to him 'Each person is to have an equal right to the most extensive total system of equal basic liberties compatible with a similar system of liberty for all' (Rawls, 1993: 82). He defends the principle of fair equality of opportunities, and proposed that all social values – liberties, opportunities, wealth, social bases, self-respect – must be equally distributed. Any unequal distribution is accepted when it represents an advantage either to all members of the society or to the most needed, in order to mitigate the negative effects of life's lotteries.

Equity has been considered a concept even more important than justice. Aristotle described it as follows:

> What is just, then, and what is equitable are generally the same, and both are good, though what is equitable is better (Aristotle, 2004: 121).

According to Rawls, equity is a fundamental requirement in terms of justice. Equity is justice. Equity exists when all participants freely define and accept the rules, benefits and charges. Any difference in benefits or charges must represent a benefit to all members of the society.

Equality is a more recent principle. However, together with justice and equity, it has become a fundamental principle. As human beings, we are not physically, mentally, psychologically or genetically equal, nor are we equal in our values or principles. But, it is generally accepted and fully desirable that we be considered equals in terms of dignity, justice, rights, opportunities, freedom, benefits, and obligations. As it has been established in Article 10 of the Universal Declaration on Bioethics and Human Rights, justice and equity are only possible if all human beings are treated equally in their dignity and rights.

Having appeared in different times and having received different meanings throughout human history, these three principles of equity, justice

and equality are basic in ethics and they have to be considered as part of any ethical system. Nowadays, it would not be possible to write any ethical or bioethical declaration without considering them.

EVOLUTION OF THE ARTICLE

Equality, justice and equity have been three of the most important ethical principles throughout human history. They represent a paradigm, a goal to be reached by our societies.

Solving inequalities, injustices and inequities has been and must continue to be a priority for our societies. Achieving this goal is an 'ideal' which has been established in many constitutions and declarations, such as the Constitution of UNESCO, or the Universal Declaration of Human Rights. In addition, justice is part of the four classical principles of bioethics and it is considered along with non-maleficence as a principle of a higher level than the other two principles, *viz.* beneficence and autonomy (Gracia, 1998). This important framework, in terms of rights and principles, supports a solid structure of moral evolution aimed at fulfilling humankind's goal of living in justice and peace. During the last 50 years, the development and application of new technologies have increased inequalities, injustices and inequities, thus creating the need to reaffirm these principles in this Declaration.

These three principles have been discussed and proposed since the beginning of the discussion. In the first draft of the structure of the Declaration, the principles were divided into general principles and other principles. Justice and equality were considered as part of the list of general principles (IBC, 2004a). The importance of justice has been set since the beginning, when it was considered that the Declaration had to fall within the framework of international human rights law, fundamental freedom, respect for human dignity and justice. At that moment, it was determined that justice is a fundamental notion that covered all rights, both between human beings and between people and state institutions. Equity was not included at this time. In the First Outline of the Text elaborated during the first and second meetings of the IBC Drafting Group, it was taken into consideration in the consultation with the Member States, and the principles described in the first draft were organized into groups of principles (IBC, 2004a). Justice was set along with human dignity and human rights as part of the fundamental principles, while equity was set along with solidarity and co-operation as part of the general principles as well. During the third meeting of the IBC Drafting Group, it was considered that the intention should be to reflect, throughout

the text, the overriding importance of human dignity; beginning with the part on general principles and with the provision concerning human dignity, human rights and justice (IBC Drafting Group, 2004a). Furthermore, in order to reinforce the notion of human dignity as a guiding thread throughout the Declaration, it was proposed that all principles set forth in the Declaration should derive from human dignity which is inherent to the human being, therefore this reference was included at the head of the general principles. In the Second Outline, the same structure was maintained for these principles (IBC, 2004b). In the fourth meeting of the Drafting Group it was considered more appropriate to speak about equality, rather than equity, while others reminded that equity was a wider notion (IBC Drafting Group, 2004b). Then, without explicitly mentioning equality in the text, it was suggested that a precise definition should be given in the explanatory note to explain that this principle is implied in the reference of human rights and human dignity. In the Third Outline of the Text, human dignity, human rights and justice were set in Article 3 as part of general (fundamental) principles (IBC, 2004c). Solidarity, equity and co-operation were set in Article 6. In the fifth meeting of the IBC Drafting Group (2004c) they were moved to Article 7, and this structure was maintained up until the sixth meeting of the IBC Drafting Group when, based on the importance and relationship between equality, justice and equity, a new article was proposed (IBC Drafting Group, 2004d). In this new article equality was included, while equity and justice were moved to the same article in order to deal with these principles together. It was determined that it was of prime importance to make explicit reference to the principle of equality, and that 'equality, justice and equity' formed a triptych that the Declaration should cover in the same article. In addition, it appeared appropriate to make a reference to equality in the area of scientific progress in the 'Aims' section of the Declaration.

THE MEANING OF THE ARTICLE

The evolution of all those principles and rights has allowed important moral advances in our societies. However, more than two centuries have passed since the right to life, health and liberty were initially proposed, and more than one century since the social rights were established. Sixty years have passed since the Universal Declaration of Human Rights was approved and, even in the practical setting, we are far from having achieved the goals of the Declaration. A very important gap continues to exist between the fulfilment of those ideals and reality. Important inequalities and inequities are still present

all around the world and some of them have dramatic consequences in the less developed countries. An example: 2,742 million people have no access to sanitation, 1,197 million people have no access to clean drinking water, 1,100 million people live below the poverty line of US$1 per day, 831 million people are undernourished, 800 million people have no access to proper health care, 780 million people are illiterate (Human Development Report, 2004), the mortality rate of the poorest children is 2.5 times higher, and 27 million children have not been vaccinated (WHO, 2006). All of them constitute old problems which have persisted even when the ethical and legal support aimed at solving them have become stronger and more widespread all over the world.

Besides these old but unsolved issues, the development and use of new technologies during the last five decades has emerged as a new reality. This new reality has brought important benefits in terms of reducing mortality and improving the quality of life for millions of people all over the world. But paradoxically, while technology grows and more resources are available, ethical problems, inequities, inequalities and injustice are also growing, even in greater proportions than progress (Human Development Report, 2005). An inherent tension exists between technical and ethical realities. The new technical advances, which have been so useful in improving the quality of life, have been inefficient in solving this problem, and have been more of a hindrance than a help. A new set of ethical problems that increases inequities, inequalities and injustice is added to the well-known list that was described above. A few examples are mentioned.

Beginning and end of life

New technologies used at the beginning or at the end of life have exposed important concerns about their uses (Callahan, 2003). The frozen embryos produced from new fertilization techniques, stem cells, therapeutic cloning and gene therapy have created new questions regarding the benefit of using these techniques, which could solve so many clinical problems but at the same time could harm societal values such as the dignity of a human being, right to life, discrimination, and confidentiality (Sandel, 2004). At the end of life, we have useful resources which allow us to treat patients who it would have been impossible to treat a few years ago. These techniques have permitted to prolong many patients' lives as well as improve their quality of life, but sometimes the same techniques, rather than saving lives might just contribute to prolonging the process of dying, increasing suffering and costs.

AIDS and HIV

Many patients with diseases such as AIDS suffer from discrimination, stigmatization, and inequities in terms of access to the treatment they need. A quarter of a century has passed since the first case of AIDS was reported and, since then, 65 million people have been infected and more than 25 million have died of AIDS. Ninety-five per cent of these infections and deaths have occurred in developing countries. Despite the important programmes developed by the United Nations and despite the recent gains in new treatments, only about one out of five people in low- and middle-income countries who need retroviral drugs receive them (Merson, 2006).

Evidence-based medicine

Despite the important biotechnological advances, many patients do not receive treatment based on evidence, or they receive no treatment at all. Many preventive treatments are not used, resulting in future complications which need to be treated using more expensive methods. Some patients are exposed to expensive treatments simply because the technology exists without any certitude about the benefits of these treatments. Inequalities in treatments and diagnostic methods based on race, gender, economic status, or place of residence are evident and scientifically proven (see, for example, Peterson, 1997, and Bach, 1999). Many people died due to errors in the actual health care system. The American Medical Association reported in the year 2000 that 44,000 to 96,000 patients died in the United States as a consequence of medical errors. It has been proven that most of these problems occur as a consequence of the complexity of the medical systems. A new paradox has appeared: at the same time as development increases, morbidity, mortality, inequalities, and inequities also increase (Institute of Medicine, 1998; Kohn, Corrigan and Donaldson, 2000; McNeill, 2001; Starfield, 2000).

Changing relationships

A more horizontal model of human relationships aimed at promoting and respecting equality between all human beings has substituted the classical vertical human relationships which dominated most societies for many centuries. This important change, which could be considered as one of the most relevant advancements in terms of moral evolution, has brought important benefits regarding equality and other rights, but it has also opened new questions and concerns about how to manage the growing tension

that is produced when the high cost of using new techniques needs to be conciliated with human rights, quality care, and distributive justice. At the same time, patient autonomy is frequently set aside. An important percentage of patients do not receive adequate information about treatment or diagnostic methods which they will be submitted to, or the information they receive is not understandable to them (Azoulay and Sprung, 2004; D'Empaire, 2001). Sometimes they are not consulted, whereas other times their will is not fully respected.

Health care expenditures

Health care expenses have risen dramatically all over the world. In the United States, federal health care expenses rose from US$2.9 billion to US$411.5 billion between 1960 and 2000. The same pattern can be observed in many countries. This increase in health care expenses has placed health care systems in considerable peril and it has had a negative effect on medical care, in terms of equality, justice, equity, and quality. During the last decades, many countries have moved from a publicly-funded health care system to a privately-funded system, thus increasing inequality between those who have and those who have not.

APPLICATIONS OF THE ARTICLE

These new realities need new moral referents. The classical principles and rights need to be applied to specific aspects and problems which have emerged as a consequence of biotechnological development and its application. In this setting, different Declarations have been adopted to address these issues. The Universal Declaration on Bioethics and Human Rights is the first Declaration regarding general bioethical aspects and human rights approved unanimously by 191 Member States of UNESCO. This Declaration re-assumes the important challenge of pursuing the accomplishment of these principles: equality, equity and justice, as well as others, in the context of the development and uses of biotechnology and its relationship with human life. It addresses classical principles and rights to the specific situations and problems that emerge from biotechnology. Well-known principles like justice, equity, and equality are linked to new specific problems (some of which are described above). As a consequence, when advancing and applying scientific knowledge and associated technologies, all human beings have to be considered equally and treated justly and equitably. Accomplishing this goal means, first of all, respecting different principles that are described in the Declaration. In other

words, in the context of applying new technologies, all human beings equally deserve that their human dignity, human rights, and fundamental freedoms be fully respected. The technologies' direct and indirect benefits must be clearly and scientifically spelled out and their potential harm reduced. Each person's autonomy must be equally respected as well as his or her human vulnerability, personal integrity, privacy and confidentiality. Discrimination and stigmatization must be avoided and cultural diversity and pluralism respected. Reaching these goals represents respect for the human beings and, as a consequence, the fulfilment of the requirements of equality, justice, and equity. In order to respect justice and equity all previous principles listed above (human dignity, human rights, autonomy, beneficence, no harm, integrity, privacy, confidentiality) have to be equally respected by all human beings. In other words, fulfilment of all those principles is required to respect equality, justice and equity.

Special consideration is needed on the grounds of social responsibilities (Article 14 of the Declaration). This article sums up a list of basic needs which have to be given to all, as a minimum, if we want to treat each human being equally and justly. Addressing these needs constitutes one of the greatest challenges that in terms of equality, justice, and equity must be solved. In its Preamble, the Declaration clearly expresses the aim of 'developing new approaches to social responsibility to ensure, whenever possible, that progress in science and technology contributes to justice, equity, and to the interest of humanity'. Article 14 of the Universal Declaration on Bioethics and Human Rights calls once again for the reinforcement of our compromise, as human beings, in reducing these problems. According to Article 14, we must, as human beings, reinforce our efforts in reducing poverty, illiteracy, unemployment, access to clean water and food. The progress in science should mitigate these problems rather than exacerbate them. The questions are: How can the negative effects of biotechnology on poverty, unemployment, food, and water sources be reduced? How could the benefits of biotechnology be used to diminish these problems? In order to answer these questions we need to increase co-operation, solidarity, and sharing of benefits. One of the main issues regarding bioethics is the actual concern about how scarce resources must be managed in order to guarantee a just and equitable health care system. Important inequalities and inequities exist in terms of access to quality health care in less developed countries. Meanwhile, serious deficits in the quality of care have been reported in developed countries.

The development of new diagnostic and therapeutic approaches has improved the health, life expectancy, and quality of life of many people around

the world. But at the same time, the costs of medical care have increased expenses far beyond the limits of any realistic budget, even in the richest countries. The increase in health care costs reduces the opportunities of many patients to receive the treatment they need (Asch, Kerr, Keesay, Adams and Setodgi, 2006). Everyday, there is more and more technology which is used for less people because of the increase in costs. As progress grows, health care systems become more unfair and inequitable. The enormous investments in biomedical research will probably accelerate the rate of technological development in medicine and, as a consequence, the inequalities in accessing it. There is a growing proportion of aging people, an increase in patients' demands for care, and serious problems in terms of definitions about how and for whom the new technologies should be used. This dilemma constitutes practical issues which are becoming important ethical questions. Even if it is accepted that full equality in accessing the best possible care will not be achievable, nowadays, each member of society, irrespective of his or her economic position, should have equal access to an adequate, although not maximal, level of health care. In order for a health care system to be just and equitable, it needs, first at all, to be efficient in terms of cost-benefit. This means that there must be an efficient management of the limited budget in order to cover the basic needs as a minimum. Important ethical questions must be raised and discussed. Should all the new technologies be available to all patients? Are the new medical techniques being used to save people who have good chances of having an acceptable quality of life or, rather, are these new treatments being given to persons with a poor future in terms of life expectancy and quality of life? Today, it is accepted that some rationing in health care is needed. A decent minimum level of care has to be defined. In such a case, what criteria must be followed? Will it be possible to accept a trade-off? In practical terms, is it possible to guarantee the highest attainable standard of health care? What does the highest attainable standard mean? What is health? Which are the real goals of medicine in the twenty-first century? What must be considered just in the application of new technologies? None of these questions have an answer yet, and answering them will require, first of all, an intense educational programme which should include all members of society, followed by a wide deliberative process. This process should be focused on efforts to re-define the concepts of heath and illness, to understand technology's limits and to set forth resource allocation strategies that clarify the limits of patients' rights regarding the use of new technologies. But above all, the deliberation process must be used to redefine new reasonable goals of medicine (Gracia, 2004).

The Universal Declaration on Bioethics and Human Rights offers a new starting point, and a new opportunity to reflect about ethical principles. As we know, adopting principles will not solve current problems, but it should facilitate discussions, by using the ethical framework offered by the Declaration. An important gap still exists between those ideal principles and our actual way of thinking and dealing with new issues. The ethical framework is already written, but it will be necessary to apply it to specific problems, taking into account cultural diversity. To accomplish this goal is the way forward if we really want to have a more equal, just, and equitable world.

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Chapter 13

ARTICLE 11: **NON-DISCRIMINATION AND NON-STIGMATIZATION**

Glenn Rivard

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.

DEVELOPMENT OF THE ARTICLE

Article 11 of the Universal Declaration on Bioethics and Human Rights addresses two related issues, discrimination and stigmatization, which are defined in relation to violations of human dignity, human rights and fundamental freedoms. The need to adopt a principle addressing discrimination and stigmatization was identified from the earliest stages of the development of the Declaration. The initial report of the International Bioethics Committee (IBC, 2003) on the subject of a declaration examined the need for, and the scope and structure of, the proposed international instrument, and recommended the development of what would eventually become the Universal Declaration on Bioethics and Human Rights. In particular, paragraph five stated, '… modern bioethics is indisputably founded on the pedestal of the values enshrined in the Universal Declaration of Human Rights (1948)'; this, of course, includes Article 7 addressing discrimination. Issues identified in the IBC report as relevant to the development of an international instrument pertaining to bioethics, for which arguably a non-discrimination and non-stigmatization article would have particular relevance, include health care, human reproduction, genetic and health care data, research involving human subjects and behavioural genetics. In reference to the last issue, the IBC report had this to say:

> There is reason to be concerned that genetic influences on such characteristics as intelligence, memory, shyness or sociability could

> be exaggerated and result in the stigmatization or discrimination of individuals or groups. A universal instrument on bioethics can impress upon the scientific community the eugenic implications of generalizations that are unfounded or premature. It can also warn people about the injustice that may result either from an exaggeration of group similarities or differences, or from the denial of such features when they have actually been established. A universal instrument on bioethics can encourage geneticists to confront the issues accurately, professionally and on the basis of the best available science (IBC, 2003).

Following the report, the IBC began the process of elaborating the draft Declaration. Both the first and second drafts provided lists of principles that included 'Non-discrimination and non stigmatization (sic)', without any elaboration of the contents of the possible article (IBC, 2004a, 2004b) This and subsequent drafts distinguished between 'primary', 'fundamental' or 'general' principles, on the one hand, and principles seen as derivative of, or of more specific application than, these primary principles. The non-discrimination and non-stigmatization article was seen as belonging to the latter category. The final, adopted declaration dropped this distinction between types of principles, however.

The first draft language of the non-discrimination and non-stigmatization article appeared in Article 9 of the third IBC draft of the Declaration (IBC, 2004c). It read as follows:

> In any decision or practice within the scope of this Declaration, no one shall be subjected to discrimination based on any grounds, including physical, mental or social conditions, diseases or genetic characteristics, nor shall such conditions or characteristics be used [invoked] to stigmatize an individual, a family or a group.

In comparison with the final version of the Article in the adopted Declaration, this early draft differs most markedly in its listing of specific included grounds of discrimination. This list differs markedly from the grounds of discrimination in the Universal Declaration of Human Rights and other precursor international human rights instruments. Arguably, it evidenced a desire to identify grounds that are most pertinent to the field of bioethics. Equally, however, it ran the risk of isolating the treatment of discrimination in the field of bioethics from the mainstream of established human rights law. In light of this, it would appear that the eventual decision to revise this Article to make it more consistent with human rights law will prove to be the

right one. This incorporates the principles of equality in dignity and human rights, equality before the law and the right to equal protection of the law. Established grounds of discrimination already apply to the more specific conditions listed in this early draft of the article. Of particular relevance is discrimination based on race, sex and national or social origin.

The fourth draft of the Declaration (IBC, 2004d) saw further elaboration of the article (now Article 10), as follows:

> In any decision or practice, no one shall be subjected to discrimination based on any grounds, including gender, age, disability or other physical, mental or social conditions, diseases or genetic characteristics, and intended to infringe or having the effect of infringing human rights, fundamental freedoms or human dignity of an individual, nor shall such conditions or characteristics be used to stigmatize an individual, a family, a group or a community.

This draft extended the list of specific grounds of discrimination, and it may have been this process that eventually led the Parties to omit any reference to specific grounds in favour of referencing established international grounds of discrimination, out of concern that any list would either be incomplete or be seen as an attempt to create new grounds of discrimination. This draft also sees, for the first time, the reference to 'intended to infringe or having the effect of infringing human rights, fundamental freedoms or human dignity', language which is reminiscent of that found in the Convention on the Elimination of All Forms of Racial Discrimination and the Convention on the Elimination of All Forms of Discrimination Against Women. The use of this language begins the process of drawing this article more closely to established human rights law, by referencing both direct and indirect discrimination and by clarifying that distinctions, to be discriminatory, must impair the human rights, fundamental freedoms or human dignity of the person.

The Draft Declaration, as developed by the IBC, was first the subject of review by States at the Joint Session of the IBC and the IGBC, held in January 2005. The non-discrimination article appeared to attract little, if any, discussion at that meeting, judging from the fact it is not mentioned once in the meeting report (IBC Joint Session, 2005). The subsequent meeting of the IBC, at which changes to the draft were discussed as a result of the joint meeting with the IGBC, also did not appear to address this article to any significant degree (IBC, 2005a). Despite this, the final draft of the IBC Declaration, arising out of these two meetings, included significantly new wording for this article (now Article 8)(IBC, 2005b):

> In any decision or practice, no one shall be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall such grounds be used to stigmatize an individual, a family, a group or a community.

As can be seen, the enumeration of specific grounds has been dropped from the article. The references to intent and impact remain, however, as means of anchoring the article to established human rights law.

From this point forward, the drafting of the Declaration passed from the IBC, a committee of experts, to the representatives of UNESCO Member States, who finalized the Declaration in a process of negotiations that concluded with adoption of the instrument in the fall of 2005. The report of the first governmental session (Report expert meeting, 2005a), held in April 2005, refers to discussions of direct relevance to the non-discrimination and non-stigmatization article. Paragraph 21 of the report summarizes the discussion on the general issue of the relationship of the Declaration to human rights, as follows:

> With regard to Article 4, all speakers recognized the importance of affirming human dignity, human rights and fundamental freedoms as a basic principle in the field of bioethics. Some delegates wished to include mention of the respect for human life, considering this to be the basis of human dignity and human rights.

Paragraph 25 of the report addresses the discussion on the non-discrimination article:

> With regard to Article 8 on non-discrimination and non-stigmatization, emphasis was placed on the protection both of individuals and families, groups or communities. Some delegates called for the reintegration of the list of grounds for discrimination contained in the previous version of the text in order to reinforce the principle. Furthermore, some insisted on making reference to situations of discrimination and stigmatization already existing in society so that this principle could also be applied to such situations. It was also proposed to clarify terminology, and to replace the terms 'no one' and 'individual' with 'person'.

Government officials met again in June, 2005. The discussion on the non-discrimination article is summarized in paragraph 23 of the meeting report (Report expert meeting, 2005b):

> Article 8 did not appear to raise any major divergent points of view. The proposal made by certain delegates to include a reference to 'unfair' discrimination was not retained since in international human rights law, the notion of discrimination covers situations of unfair treatment and since the text as drafted did not seem equivocal as to positive discrimination. Moreover, some delegates felt that it was important to place emphasis on those to whom this principle is addressed – the individual, families, groups and communities – who should be protected as well as both cases of stigmatization and discrimination. Others did not seem favourable to this proposal to the extent that the Declaration cannot create a collective right that does not presently exist in international law. After the discussion of an informal group called by the Chairperson and coordinated by the representative of Brazil, the meeting approved the article as presented in the Declaration.

Although the summary of the discussion is not clear on this point, it was at this meeting that the non-discrimination and non-stigmatization article was settled in its final form. As the drafting of the overall Declaration had proceeded, it became possible to simplify the drafting of this particular article because a reading of the entire Declaration makes it clear that the non-discrimination and non-stigmatization principle is embedded within the established international law of human rights.

EXPLANATION OF THE ARTICLE

As with the entirety of the Universal Declaration on Bioethics and Human Rights, an understanding of this particular article requires that it be read in the context of the entire instrument. This generally applicable principle of interpretation is made explicit in Article 26, which provides that, '[t] his Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.' Without reiterating the entirety of the Declaration, therefore, what are the provisions of the Declaration that are particularly relevant to an understanding of Article 11?

First, of course, is Article 1, pertaining to the scope of the Declaration, because the language of Article 11, if read in isolation, is so broad that it could well be misunderstood to be a provision of general application with respect to discrimination and stigmatization. The Article, however, like all the others in the Declaration, is circumscribed in its application to matters

falling within the scope of the Declaration as set out in Article 1. That is, the injunction against discrimination and stigmatization is in reference to the resolution of 'ethical issues related to medicine, life sciences and associated technologies as applied to human beings' and allows for the consideration of 'social, legal and environmental dimensions' (Article 1(a)). Further, the Article applies to State Parties to the Declaration. It also 'provides guidance' to individuals and organizations that address bioethical issues in the course of their work or responsibilities (Article 1(b)). As indicated by the *chapeau* to the Principles section, the principles outlined in Article 11 are to be respected by State Parties and non-States in any decisions or practices that fall within the scope of the Declaration as set out in Article 1.

Just what is meant by 'discrimination' and 'stigmatization' in Article 11? As noted above, the use of these two terms clearly refers to two distinct concepts.

Discrimination

'Discrimination', of course, is a legal concept of long standing within human rights law, both in international law and in the domestic law of States which adhere to international norms of human rights law. The foundational instruments of international human rights law are all referred to in paragraphs 5 and 6 of the Preamble, including the Universal Declaration of Human Rights, as well as the International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights, the Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination Against Women and the Convention on the Rights of the Child.

In particular, Article 1 of the Universal Declaration of Human Rights provides that, 'All persons are born free and equal in dignity and human rights'. Article 2 provides that everyone is entitled to the rights and freedoms set forth in the Declaration, 'without distinction of any kind such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.' Further, no distinction on the basis of the country or other jurisdiction to which a person belongs may be made. Article 7 specifically addresses discrimination, and provides:

> All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to discrimination.

In this fashion, the grounds of prohibited distinctions as set out in Article 2 are imported into the prohibition against discrimination established in Article 7.

Subsequent conventions have specifically addressed discrimination on the basis of race and gender. The Convention on the Elimination of All Forms of Racial Discrimination commits State Parties to not engage in racial discrimination, including through any public authorities or institutions, to not support any racial discrimination by any person or organizations, as well as to take positive measures to bring to an end racial discrimination by any person or organization (Article 2). Racial discrimination is defined as, 'any distinction, exclusion, restriction or preference based on race, colour, descent, or national or ethnic origin which has the purpose or effect of nullifying or impairing the recognition, enjoyment or exercise, on an equal footing, of human rights and fundamental freedoms in the political, economic, social, cultural or any other field of public life.' The Convention on the Elimination of All Forms of Discrimination Against Women adopts a similar approach to State obligations, and defines discrimination against women in similar terms to the definition of racial discrimination in the Convention on the Elimination of All Forms of Racial Discrimination, except, of course, that it applies to '… any distinction, exclusion or restriction made on the basis of sex…' (Article 1).

Article 11 of the Universal Declaration on Bioethics and Human Rights has the benefits of simplicity and of being embedded within the larger body of established international human rights law. There is no attempt to duplicate the entirety of international law pertaining to discrimination, nor is there any need, as it is clear for several reasons that the prohibition against discrimination makes reference to this larger body of law. In addition to the specific preambular references to existing international human rights instruments, paragraph 7 of the Preamble provides that the Declaration 'is to be understood in a manner consistent with domestic and international law in conformity with human rights law'. Further, Article 2(C) provides, as one of the aims of the Declaration, that it is to 'promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law'. These references not only embed Article 11 within this larger body of long-established international law, but also serve to remind us that the Declaration does not create new human rights, including new grounds for discrimination. (All the more so as the document is a declaration and not a convention.) With reference to human rights, and discrimination in

particular, the Declaration serves to apply this body of law to the particular realities raised by ethical issues related to medicine, life sciences and associated technologies.

Stigmatization

What of the concept of 'stigmatization'? This concept appears to have no precursor in the general body of international human rights law. It does, however, appear in the International Declaration on Human Genetic Data. Both this Declaration and the Universal Declaration on the Human Genome and Human Rights, along with the Universal Declaration on Bioethics and Human Rights, make a sort of triumvirate of UNESCO declarations in the field of bioethics. The two previous declarations are specifically referred to in Paragraph 5 of the Preamble of the most recent declaration.

Interestingly, the concept of stigmatization does not occur in the Universal Declaration on the Human Genome and Human Rights, the first document in this triumvirate. However, Article 7 of the International Declaration on Human Genetic Data (2003) provides that:

> a. Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing, human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities.
> b. In this regard, appropriate attention should be paid to the findings of population-based genetic studies and behavioural genetic studies and their interpretations.

As with Article 11 of the Universal Declaration on Bioethics and Human Rights, this provision clearly distinguishes between discrimination and stigmatization. Given the broad scope of the concept of discrimination, just what is meant by the references to stigmatization in these two declarations, particularly the most recent declaration? 'Stigmatization' is not a defined term in either of the declarations, but the Oxford English Dictionary Online (http://dictionary.oed.com) defines 'stigma' as '[a] distinguishing mark or characteristic (of a bad or objectionable kind)' and 'stigmatize' as 'to call by a disgraceful or reproachful name; to characterize by a term implying severe censure or condemnation'. The Merriam-Webster On-Line Dictionary (http://www.m-w.com/) defines 'stigma' as 'a mark of shame or discredit' and 'stigmatize' as 'to describe or identify in opprobrious terms'. 'Opprobrium'

meaning, of course, 'something that brings disgrace'. With respect to the Declaration, therefore, the term would refer to communications or other conduct that negatively characterizes a person or group in the context of the application of medicine, life sciences and associated technologies and in such a way as to infringe upon their human dignity, human rights or fundamental freedoms.

Arguably, such conduct, if carried out by a State or agents of a State would amount to discrimination as understood in international law, although there may be some limited room for State agents to stigmatize individuals or groups without impacts significant enough to be considered discriminatory. More likely, however, stigmatization, as a discrete activity from discrimination, would be carried out by non-State individuals and organizations, and this reference in Article 11 would be primarily addressed to such persons. Stigmatization amounts to a negative labelling of a person or group, but with impacts of a limited or indirect nature such that the conduct may not amount to actual discrimination as understood in law. This acknowledges the potential of bio-science procedures, such as genetic testing, to cause harm to individuals and groups that, nonetheless, may fall short of discrimination as understood in law.

This interpretation of the concept of stigmatization is consistent, as well, with the fact that the Universal Declaration on Bioethics and Human Rights is not intended to expand the scope of human rights law, but rather to aid its application to the resolution of ethical issues in the fields of medicine, life sciences and associated technologies.

The concept of stigmatization has been addressed by other world and regional bodies. The European Union identifies the need to address stigmatization in many of its documents, including, for example, the Conclusion of the Employment, Social Policy, Health and Consumer Affairs Council of 2/3 June 2003 on combating stigma and discrimination in relation to mental health (European Union, 2003). In contrast, the Charter of Fundamental Rights of the European Union prohibits 'discrimination', but does not mention 'stigmatization', an approach consistent with the view that the former is a legal concept and the latter a social concern (European Union, 2000).

The concept of stigmatization appears frequently in the work of the WHO, as well. Reports and other documents of this organization refer to stigmatization in contexts as diverse as HIV and AIDS and the psychiatric costs of war. The on-line document, *Gender and Genetics*, in its section on 'Genetic Stigmatization', states that persons who are 'carriers of a recessive

gene associated with disease, or who are affected by a genetic condition, may face a range of social and psychological consequences, including stigmatization by the community' (WHO, 2007).

APPLICATION OF THE ARTICLE

As noted earlier, the IBC in its initial report on the feasibility of developing a bioethics declaration, elaborated on the importance of addressing discrimination and stigmatization as a result of developments in behavioural genetics (IBC, 2003). The principle of Article 11, however, will also give guidance to the resolution of a wider range of bioethical issues. In the context of research, for example, the selection of research subjects should not be influenced by a belief that members of a given group are less deserving of protection from the risks associated with research than others. Public health measures should be designed primarily on the basis of a risk/benefit analysis, rather than undertaken for the benefit of one group to the exclusion of another which also faces the same or a similar health risk. Article 11 is, of course, relevant to the consideration of any measures designed to address gender selection in the application of assisted human reproduction procedures or pre-natal diagnosis. The guidance provided by Article 11 should lead the media to exercise care in contextualizing the findings of genetic studies in order to avoid stigmatization of population groups.

In these and other situations, however, it is important to recall that not all distinctions amount to a violation of human dignity, human rights or fundamental freedoms. Distinctions based upon accepted scientific evidence may be justified. For example, the projected trend in the development of designer drugs to match particular genotypes may be well justified as a means of enhancing their effectiveness or reducing their risks. Care must be taken, however, to avoid the systematic development of medicines for one group within the population while neglecting the needs of others. Equally, public health measures that correctly target the at-risk population would not likely be considered to violate their human rights, but the neglect of a population group's health risk on a prohibited ground of discrimination, such as race or sex, would likely do so.

CONCLUSION

In conclusion, then, concern for the potential of the bio-sciences to contribute, intentionally or otherwise, to discrimination and stigmatization of individuals and groups was present from the earliest discussions leading to the development of the Declaration. The importance of addressing this issue appears to have

always been accepted, with the only discussion occurring around how best to frame the protection from such conduct. In the end, the article was reduced to its fundamentals, an approach that was made possible given the general reading of the Declaration. This firmly anchored the Declaration within the tradition of established international human rights law and provided robust meaning to this deceptively simple article.

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Chapter 14

ARTICLE 12: **RESPECT FOR CULTURAL DIVERSITY AND PLURALISM**

Michel Revel

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.

INTRODUCTION

Our generation witnesses an increasingly rapid progress in the mastering of new biomedical technologies, which prevent, circumvent or overcome malfunctions in the human body, its genome or reproductive system. The advent of these technologies raises continuously new dilemmas, which are often of a fundamental ethical nature, especially when one fears that applying these technologies may impinge on traditionally valued moral practices and principles. Hence, bioethics has become an essential endeavour, providing an interdisciplinary forum where the issues can be debated at the legal, philosophical and medico-scientific level, where benefits and dangers can be defined and where guidelines can be proposed to governments and societies for delimiting the permissible. The principles that guide the bioethical reflection are foremost anchored in the respect of the Universal Declaration of Human Rights (1948), which provides an internationally recognized moral and legal framework within which bioethical guidelines can be formulated. However, more specific and particular viewpoints on morality and philosophy of life are often at the heart of the bioethical debate, these viewpoints being rooted in diverse cultural values, in religions and at times in national legal systems. Harmonizing the universal and the particular becomes then a necessary but difficult task; in some cases a consensus may be achieved, but in others it is only possible to state a pluralism of standpoints. In all cases, it is essential that the particular perspective of each belief be presented in a rational, intelligible

way that can be understood if not accepted by all sides. At the heart of this difficult and complex mission lies a ponderous interrogation: Is it at all possible to take into account ethical views which conflict with each other, even if they may sometimes appear to endanger universally accepted norms? In other words, why is respect of cultural diversity and pluralism important, and why should it be part of the Universal Declaration on Bioethics and Human Rights?

THE PROBLEMATIC OF CULTURAL DIVERSITY

The Universal Declaration on Cultural Diversity adopted in 2001 points to a dual interdependence of human rights and cultural diversity. Article 4, entitled 'Human rights as guarantees of cultural diversity', proclaims that:

> The defence of cultural diversity is an ethical imperative, inseparable from respect for human dignity. It implies a commitment to human rights and fundamental freedoms, in particular the rights of persons belonging to minorities … No one may invoke cultural diversity to infringe upon human rights guaranteed by international law, nor limit their scope (UNESCO, 2001).

First, human rights – that are universal – guarantee the particular expression of individual cultures, being understood (as reaffirmed in the Preamble) that 'culture should be regarded as a set of distinctive spiritual, material, intellectual and emotional features of society or a social group and that it encompasses … lifestyles, ways of living together, value systems, traditions and beliefs'. But conversely, there is a need to protect the universality of human rights from a claim that such diverse features of societies or social groups could justify contravening human rights as guaranteed by international law. Such a dual relationship indeed reflects some ambivalence in the value of cultural diversity.

But the dual relationship also stems from a difference in nature. Human rights are natural-born rights and are defined by international law, unlike culture. In the words of Béji:

> Human rights are defined as natural rights, at the opposite of cultural rights … Human rights emerge from erasing cultural differences, from ending the hierarchy of cultures. They affirm that the cultural argument cannot claim the authority of a legal principle. All men are free and equal in rights, whatever their origin, their language, their beliefs … Human rights are subject to a civil law that controls them and is

> applicable to all, whereas cultural rights are left to the free appreciation of their proponents (Beji, 2004: 314).

Such considerations will assuredly be of greater relevance when ethical issues are at stake, and more so when these impinge upon life matters, which is the essence of bioethics. One may therefore ponder the reason for including an article on 'Respect for Cultural Diversity and Pluralism' in the Universal Declaration on Bioethics and Human Rights. In the preliminary draft elaborated by the IBC, Article 7 stated that:

> Any decision or practice shall take into account the cultural backgrounds, school of thoughts, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, such considerations shall not 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 (IBC, 2005).

In the final text adopted by the General Conference of UNESCO, the language (in Article 12) was slightly modified. The reference to decision or practice has been deleted, as well as the mentioning of backgrounds, schools of thought, traditions, and beliefs.

What is the importance of a principle respecting a pluralism rooted in cultural diversity when dealing with ethics of science, particularly of life sciences? Does it not deny bioethics to be, like the science it reflects upon, a set of common truths for all? Does it not contradict the need for a clear and unified line of action? Such apparent contradictions arise from the recurrent error of considering that principles are in competition with each other, that they are incompatible in essence and force us to make a choice between them. On the contrary, as is said in the Declaration, '…principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances' (Article 26). This complementarity is a requirement to reach harmony. When reflecting on an issue, the principles that form the basis of the reflection may well be different and sometimes conflicting, but the essence of bioethics is to assemble the principles to build a set of harmonious rules, in which all can acknowledge sufficient elements of truth to abide by them.

UNIVERSALITY AND PLURALISM

The world in which we live is by nature pluralistic; an assembly of nations and cultures. The lessons of history, after the French Revolution of 1789 and

with greater urgency after World War II, have led humankind to proclaim universal human rights to protect the dignity, equality and liberty of all human beings. In this wake, and particularly following the atrocities of Nazi doctors, bioethics has emerged to ensure the universal respect of human dignity, human rights and fundamental freedoms for the welfare of the individual in medical practice and in the application of the tremendous progress in life sciences and technologies.

Human rights are not exempt of pluralistic interrogations, which even concern the most evident rights. Article 3 of the Universal Declaration of Human Rights ('Everyone has a right to life, liberty and security of person') is respected within the pluralism of national laws, when these include capital punishment or differently define the enormity of the crime for which a person may be deprived of life or liberty. This is not moral relativism, but 'inherent flexibility' as stated in a 1995 United Nations note on the Challenge of Human Rights and Cultural Diversity:

> Universal human rights do not impose one cultural standard, rather one legal standard of minimum protection necessary for human dignity. As a legal standard adopted through the United Nations, universal human rights represent the hard-won consensus of the international community, not the cultural imperialism of any particular region or set of traditions…Out of this process, universal human rights emerge with sufficient flexibility to respect and protect cultural diversity and integrity. The flexibility of human rights to be relevant to diverse cultures is facilitated by the establishment of minimum standards and the incorporation of cultural rights…Within this framework, States have maximum room for cultural variation without diluting or compromising the minimum standards of human rights established by law (Ayton-Shenker, 1995).

Universal principles of bioethics are often presented as four major obligations: 1) respect the autonomy in the decision-making ability of the person and hence the obligation to obtain free informed consent; 2) beneficence in intention and action, e.g. therapeutic aim; 3) non-maleficence, above all no intentional harm and minimizing non-intentional harm; 4) justice and equality, treating everyone without discrimination. While already implied in these four principles, the obligation to respect human dignity and human rights is a foremost principle of bioethics which is emphasized expressly in the titles of the Universal Declaration on the Human Genome and Human Rights, as well as the Universal Declaration on Bioethics and Human Rights.

Nevertheless, pluralism of culture and values, religious and philosophical perspectives impacts and colours the principles of bioethics. Full autonomy, in some cultures, can be seen as limited by various considerations of collective good. Without violating the principle that 'the interests and welfare of the individual should have priority over the sole interest of science or society' (Article 3(b) of the Universal Declaration on Bioethics and Human Rights), many would agree that, confronted by a pandemic spread of disease, measures such as quarantine or obligatory mass vaccination may be needed, leading to inevitable limitations of freedom and autonomy. How far benefits (beneficence) for the collectivity, rather than solely for the individual, may be allowed to extend is still part of many debates, for example on the limits of genetic screening and selection, or internment of certain psychiatric patients. Refusing euthanasia requested by patients suffering from terminal diseases may be viewed as infringing on their autonomy. Offering certain drug treatments or surgery that entail high risks may conflict with non-maleficence. Plastic surgery to comply with societal fashion may sometimes raise questions about therapeutic aims. The bioethical principles of justice and equality are often subject to local economic variables, be it in capitalistic societies (inequity in health insurance; restricting treatments for old age, e.g. dialysis) or in developing countries (lack of means).

PLURALISM APPLIED TO BIOETHICS

The limits within which particular legal systems can be at variance without infringing on human rights are determined by international law. But as regards bioethical debates – in which cultural pluralism and human rights issues may be on the line – these are often of another nature, more subtle and complex as they are rooted in philosophical or religious outlooks on the human person, and because they revolve around moral and scientific definitions of humanity which are not in the realm of international law. The two reports of the IBC for which a pluralistic approach has been specifically recommended are on the use of embryonic stem cells in therapeutic research (IBC 2001) and on pre-implantation genetic diagnosis (PGD) (IBC, 2003), topics that both affect embryos obtained by *in vitro* fertilization (IVF). Crucial issues revolve around definition of the beginning of human life: at what stage in its development does the fertilized egg, the embryo or the foetus become a person with human rights and what are these rights before pregnancy starts (e.g. IVF) or during pregnancy, when its rights have to be related to the mother's human rights (e.g. voluntary abortion). In addition, in view of

the therapeutic and diagnostic medical relevance of these areas of scientific research, the human right 'of everyone…to enjoy the benefits of scientific progress and its applications' (UN, 1966) is a complementary principle which would be violated if these fields of scientific endeavour were banned for all, solely on the basis of particular philosophical or religious beliefs which are not shared by all in this pluralistic world. Similar considerations may be applied to other fields, for example therapeutic cloning[1]. Inasmuch as tissues derived from embryonic stem cell cultures could repair damage from neurological diseases or traumas, heart infarction or diabetes, and given that the use of autologous embryonic stem cells produced by therapeutic cloning could prevent the rejection of the transplanted tissues, a pluralistic approach allowing societies the right to decide whether or not to pursue the research, but in any case compelling them to set up ethical regulations, appears to be the most appropriate course of action. This course was the one specifically adopted by the IBC in its report on the use of human embryonic stem cells in therapeutic research:

> 1. It was decided that any report which the IBC might adopt on this matter should reflect this pluralism. This report, therefore, recognises that there are very marked differences of opinion relating to embryo research. It aims to highlight the various ethical arguments with a view to facilitating the resolution, at national and international level, of a controversial matter. It recognises that the solutions adopted by national ethical committees or national legislatures may well be different. Such differences are inevitable in a pluralistic world where people may sometimes adopt ethical positions which are unacceptable to others.
>
> 52-54 … This issue has complex ramifications and the various views are obviously influenced by the concept of human life and personhood particular to each culture, religion or philosophy … Every society has the right and duty to debate and decide upon ethical issues with which it is confronted. Where there is fundamental disagreement, the society will have to decide where it stands on an issue either because the question involved relates to some fundamental value of that society or because practical considerations demand that the matter be resolved. The use of human embryos for deriving stem cells would appear to be one such issue. Human embryonic stem cell research – and embryo research in general – is a matter which each community (and this will usually mean a State) will have to decide itself. If the decision is

> reached after serious ethical debate, which allows for the expression of views in different directions, then this must be accepted if one believes in the principle of the democratic resolution of public issues. Examples of this process are afforded by IVF for fertility treatment and by pre-implantation diagnosis with embryo selection: there are differences of opinion on the ethical values involved and yet many States have decided that these medical practices are permissible.
>
> 55 … The IBC recognises that human embryonic stem cell research is a subject on which it is desirable for a debate to occur at national level to identify which position on this issue is to be adopted, including abstaining from this research…Whatever form of research involving embryos is allowed, steps should be taken to ensure that such research be carried out within the framework of a State-sponsored regulatory system that would give due weight to ethical considerations, and set up appropriate guidelines… (IBC, 2001).

The extensive emphasis on pluralism in this report, which further details religious and philosophical opinions, is an intrinsic component in the process of bioethical reflection and in its formulation of practical guidelines. Beyond the diversity of opinions on embryo status, the report establishes the ethical guidelines to follow if and wherever therapeutic research with embryos left over after IVF is permitted. Countries which do not allow extracting cells from IVF embryos have, on several occasions, drawn from these guidelines to import embryonic stem cells from other countries when they were convinced that the latter adhered to the ethical guidelines. This emphasis on pluralism is reiterated in the report on PGD (IBC, 2003). In considering these reports, it is essential to emphasize, once more, that pluralism is not moral relativism, as Polkinghorne writes:

> It is important to note that what is at issue here is not the force of universal moral principles, for all recognize the moral status of the human person. The differences arise from disagreement about how those principles are to be applied in this specific case, in particular what are the 'facts' about human personhood and the very early embryo… [there are] fundamental disagreements among people who are all genuinely seeking to act with ethical responsibility…[disagreements] located not on the surface of practical decisions, but in the profound depths of metaphysical theory about the character of humanity (Polkinghorne, 2004: 136, 138).

Pluralism in opinions similarly prevails on questions related to the end of life. The realization of the irreversibility of scientifically defined brain-death has made the donation and transplantation of vital organs a surgical procedure that daily saves many patients' lives. If, as in some cultures, death is when respiration and heartbeat cease, saving one patient would never justify killing another person. The concept of a 'life worth-living', as in debates on euthanasia in terminal illness, similarly touches the profound depths of metaphysical theory about the character of humanity. This concept may be encountered again in prenatal genetic testing, where bioethics supports the pluralistic principle, leaving the decision to the mother after informed and non-directive counselling (IBC, 1995). In such decisions, much depends on one's views on body, mind and soul, on life's potential versus biological (genetic) determination, and on 'the character of humanity'.

THE VALUE OF PLURALISM

Pluralism is itself a value, a guarantee of coexistence and mutual understanding. But it requires definition and lucid boundaries. Such are proposed by Berlin (1990):

> We are urged to look upon life as affording a plurality of values, equally genuine, equally ultimate, above all equally objective; incapable, therefore, of being ordered in a timeless hierarchy, or judged in term of some one absolute standard. There is a *finite* variety of values and attitudes, some of which one society, some another, have made their own, attitudes and values which members of societies may admire or condemn but can always…if they try hard enough, contrive to understand - that is, see to be intelligible ends of life for human beings…This doctrine is called pluralism (Berlin, 1990: 79).

Berlin states the limits in pluralism of values:

> Incompatible these ends may be; but their variety cannot be unlimited… There is a limit beyond which we can no longer understand …when the possibility of communication breaks down, we speak of derangement, of incomplete humanity. But within the limits of humanity, the variety of ends, finite though it is, can be extensive. The fact that the values of one culture may be incompatible with those of another, or that they are in conflict…does not entail relativism of values, only the notion of plurality of values not structured hierarchically…(Berlin, 1990: 79).

There is not one absolute standard for all times and all human beings. No one has the whole or only truth: tolerance and the ability to say 'I may be wrong' as well as to see and understand the truth in the other's opinion are central to the ethics of discussion, which is at the core of bioethics. Pluralism ought, therefore, to be part of bioethics in its task of prescribing how science may be applied for the good and welfare of the individual, as well as defining the limits of the permissible. However, the principles or 'ends' of bioethics should be like a building where harmonious assembly of complementary components is essential. These principles are diverse and encompass 1) respect of human rights and dignity; 2) respect for fundamental freedoms, including being asked to give informed consent; 3) receiving treatment with intent to heal (beneficence), with justice and without maleficence; 4) respect for the right of everyone to benefit from the scientific advances; 5) respect also for cultural pluralism, even for conflicting values that may impact either on the place of the individual in the collective, or on the definition of the beginning and end of life, or on what constitutes the quality of life. There are different ways to construct a harmonious building, but only a limited number of ways because if one principle is excluded or non-equilibrated, the construction will crumble. This is the limit of pluralism: no society can invoke its own cultural or political features, objectives or ends to exclude one of the principles. Let us never forget that what the Nazi doctors did was violate human dignity by discarding the very principles that are the essence of bioethics: they acted without consent, had no intention of doing beneficence to the person acted upon, acted with intent to harm, without justice and with discrimination toward Jews and other inmates. This is the real danger. A pluralistic bioethics is the opposite: it allows all to adhere and abide by all the harmoniously assembled principles.

CONCLUSION

Bioethics is an ongoing process because new ethical reflections are needed continuously as science and technology progress. Taking into account that we live in a pluralistic world, the principles of bioethics need to be valid for all communities of human beings. While being vigilant in the observation of human rights, one ought to have the wisdom not to add excessive precautions that would unnecessarily erect prohibitions, thereby negating other rights, duties and values, in particular when dealing with the promises of science for medicine and welfare. Pluralism is a value, provided there is mutual

understanding which, in the final analysis, is to succeed making one's good intentions intelligible and legitimate to all.

Endnote 1

On 8 March 2005, the UN General Assembly adopted resolution 59/280, containing in its annex the text of the United Nations Declaration on Human Cloning (a non-binding political declaration that would 'prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life') by a vote of 84 to 34, with 37 abstentions. The text had been adopted in the Sixth committee on 18 February 2005 by 71 countries in favour, with 35 against and 43 abstentions.

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Chapter 15

ARTICLE 13: **SOLIDARITY AND COOPERATION**

Alphonse Elungu

Article 13 – Solidarity and cooperation

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

The objectives of the following remarks and reflections are to determine the position of the principle of solidarity and co-operation in the Universal Declaration on Bioethics and Human Rights, to highlight its significant importance and to draw attention to the modalities of its possible, but at the same time difficult, application.

THE RELEVANCE OF THE PRINCIPLE

Article 13 formulating the principle of solidarity and co-operation is part of the 15 articles in the Declaration that are listed in the section of Principles. These principles are not hierarchical but are complementary and interdependent.

In the listing of principles, the principle of solidarity and co-operation is at the centre of principles that are related to fundamental individual freedom. We underline that in the formulation of the principle the reference to 'towards that end' following 'international co-operation' demonstrates that the latter is subordinated to solidarity. This is important since international co-operation is historically the domain of liberty, while solidarity among human beings is primarily the domain of the human being as a social being in the real world and living in nature. On the basis of this distinction we are brought into the general framework of ethics with two different levels: the first one is freedom of action within nations, the second one is co-operation between nations.

Freedom of co-operation within and between nations is liberty as defined and regulated by law. Law constitutes and establishes the free human being in its unique characteristic of agent in association with other human beings, and therefore as an agent that already necessarily is acting in co-operation

with another. It is through co-operation that the free human being becomes a citizen and is brought to discover what is common between him or herself and others, what he or she shares with others, and which bond unites him or her to others. Hence the human being establishes this co-operation as an instrument for the universal community that brings together all human beings.

Therefore there is a logic behind the subordination of freedom to solidarity that is not necessarily formal and explicit. This logic is increasingly and distinctively expressed in the view that freedom *par excellence*, that is the freedom of a citizen in a State, remains the freedom personified by the citizen – a concrete human being of flesh and bone. Freedom has to be realized by transcending itself in the search for agreements or even consensus, expressing in ever better ways the relationship that, from the beginning to the end, intimately joins it to reality.

It has to be noted that this awareness and its formulation in Article 13 of the Declaration is the appropriate expression of a general ethics of freedom – freedom that is personified, related, open but responsible for itself and its life forms, of the reality of nature and life, of 'everything' in which it participates. Ethics in general is opposed to the ethics of freedom that the dominant modernity always portrays as an absolute power originating from above reality and even life realities, and that is at work in the sciences and technologies. This ethics of freedom has to be satisfied and is limited to accompany this infinite progress of freedom; progress in itself is regarded as beneficial and liberating, but its negative effects are ignored or at most managed in a pragmatic manner. Ethics in general contrasts with the ideology of liberty and the absolute power of the individual; it is geared to the practice of responsible, plural, multidisciplinary and multidenominational freedom which seeks concordance with itself and with its inventions, as well as with nature and its laws. Ethics in general also contrasts with the ethics of freedom, resulting in a long experience of struggle against absolute political power: human rights. Ethics in general brings in, against the ethics of freedom, international human rights law and focuses on the human being above all.

EVOLUTION OF THE ARTICLE

Already in the first meeting of the IBC Drafting Group in April 2004 reference was made to solidarity as one of the general principles that should be included in the future Declaration (IBC Drafting Group, 2004). In the First Outline of a Text (IBC, 2004a), solidarity was mentioned as one of the

four general principles, within the same context as equity and co-operation. In the Second Outline of a Text, this has not essentially changed, although the number of general principles has increased to five (IBC, 2004b). An elaborated text appeared in the Third Outline of a Text (IBC, 2004c) as one of the 'general [fundamental] principles':

> **Article 6 – Solidarity, equity and cooperation**
>
> Any decision or practice within the scope of this Declaration shall respect the solidarity of humanity, ensure equity and encourage international co-operation [, in order *inter alia* to avoid discrimination and stigmatization of an individual, a family or a group].

The text of the article still refers to avoidance of discrimination and stigmatization but between brackets. Later these two concerns were formulated in a separate article.

The text of the draft article slightly changed in the Fourth Outline of December 2004 (IBC, 2004d). Instead of speaking about 'humanity', reference is made to 'human beings'. Also 'equity' is no longer mentioned (it moved into a separate article) as is clear in the revised title of the draft article:

> **Article 14 – Solidarity and cooperation**
>
> Any decision or practice shall pay due regard to the solidarity of human beings and encourage international co-operation to that end.

The Preliminary Draft Declaration, issued by the IBC a few months later in February 2005, presents essentially the same text (IBC, 2005).

The final text of the article adopted by the IBC has been subjected to a few drafting changes by the governmental experts in their second meeting in June 2005. An intensive discussion focused on the wish of some delegates to add a paragraph that would guarantee that transnational and international research aims at satisfying the needs of the host countries, and also to encourage transnational and international research to strive towards contributing to the resolution of global problems to health. Finally, the experts decided that such a provision would be of paramount importance to the Declaration, particularly for developing countries. They decided to include these issues within a separate article on transnational practices (Article 21) and not to include these concerns in the present article on solidarity and co-operation (Report expert meeting, 2005). The text adopted by the governmental experts was subsequently adopted by the General Conference and has therefore become part of the final Declaration.

MEANING OF THE PRINCIPLE

UNESCO, in its practical and theoretical search for universal norms in bioethics, has developed a universal norm that is perfectly expressed in Article 13 of the Declaration. This special norm is freedom, although not individual fundamental freedom that modern ideology presents as the pure power originating from the absolute individual, outside and above all reality.Rather a freedom personified in a concrete real individual, who is at the same time agent, is displayed in its singularity and complementarity with the freedom of others, that is in co-operation under the supreme law of the political institution and its social framework: the nation. Finally, a freedom that is conscious and restrained at this institutional level of action becomes co-operation within and between nations and creates the sacred relationship that unites it to other free stakeholders, who are concrete human beings.

The concrete human being, the subject of autonomous action contrasted to other autonomous actions under the mediation of the law and public institutions, becomes a free self-conscious citizen working only in co-operation with others in his/her and the general interest; a citizen capable in the inevitable case of conflict of interest and values to search collectively with others, rules and principles, justifying reasons, fundamental values and able to manage agreements at best consensus, based on the basic relationship between unity and diversity of each and every one individually.

We can understand that with such a 'holistic' conception of the human being and of freedom within the general historical and institutional context of (national and international) societies, of freedoms regulated by laws or constitutional states, we can witness with the elaboration by UNESCO and the adoption by the international community of the Declaration, the birth of a general ethics of humanity at the service of human beings. This is exactly what makes this Declaration a really universal declaration on bioethics and human rights, a universal instrument at the disposal of everyone: states, communities, groups, families and individuals. They are stimulated to co-operate at all levels with the intention of saving humanity from the evils of modernity, that is the modern ideology of the absolute individual: violence and war, demoralization and de-sacralization, alienation and slavery, domination and exploitation, social disruption and loss of meaning. Above all, this Declaration encourages co-operation, having in mind future human beings and the advent of another world.

APPLICATION OF THE PRINCIPLE

The formulation of the principle of solidarity and co-operation has been important for the Declaration because it is a component of the conceptual framework of principles and procedures intended to 'guide States in the formulation of their legislation, policies or other instruments in the field of bioethics' (Article 2(a)). The direct application of such a principle is therefore only possible at the level of global society through co-operation among States. At the state level, co-operation will be possible among communities, groups and families. Ultimately, encouraged by the State, this co-operation and this solidarity can become a reality at the individual level.

The correct application at all levels of all other principles of the Declaration (which are, by the way, 'complementary and interrelated') will not only facilitate but also realize the effective application of the principle in Article 13. This will contribute to making States transparent and more ready to promote international co-operation in regard to questions, decisions, solutions and problems of present-day bioethics.

This is undoubtedly useful but insufficient. We have also observed in this principle a resource used by the persons who drafted the Declaration in their search for universal norms in the area of bioethics to orientate themselves in a non-dogmatic way towards a norm that is objectively real and that may be imposed on the freedom in a critical way – within plural and multi disciplinary discussions and debates.

The power of the State and its competence in all domains necessary for the adequate application of the principles of the Declaration demands that the state, in the application of these principles and in co-operation with other states, will submit itself to 'solidarity among human beings'. In the spirit of UNESCO, one can say that the application of the principle addresses at this moment and this level the international community in its cultural but also biological diversity.

However, the application of the principle also depends at the same time on the process of subordination of the states to international co-operation and the authority of the international community, which are required by and based on the solidarity of human beings. This demonstrates immediately the condition *sine qua non* of the general ethics of humanity: States that are sufficiently powerful and free and that can guarantee through democratic co-operation the primacy of the general interest over private interests.

It is obvious that the contemporary context of the historic divide of humanity in higher and lower degrees of humanity as well as the division of

the world in the 'North' (developed countries) and the 'South' (underdeveloped countries), the fracture of society into have's and have-not's, of dominating masters and exploited poor workers makes the application of the principle so difficult that it even seems vain and illusive, and to some perhaps impossible.

But this principle is in fact already applied and on its way to being realized, because it is asserted at the level of international institutions and organizations, being acutely aware of the challenges to be faced, as an effective remedy against the plagues of humanity and as an indispensable condition for its survival and harmonious development in the world. Among the examples that we can only mention without further developing them is, first of all, the Universal Declaration on Bioethics and Human Rights, initiated and adopted by UNESCO. Other examples to be mentioned are in the same line of thinking: the fight against corruption through the establishment of democracy at all levels; the struggle for co-operation and fair trade and against subsidies that are alienating the 'free' market to the benefit of the rich and to the detriment of the general interest which is aimed at equitable international co-operation in the service of solidarity among human beings; the fight at the level of the WHO against pandemics such as AIDS, against the migrations of viruses; and the capacity-building in the area of public and global health.

These examples may provide an illustration of the beginning of hesitant, but firm, application of the principle of international co-operation on the basis of solidarity. One can notice in these examples the emergence of human freedom, responsible for itself, from the reality of its diversity. This freedom regards the public interest itself under the perspective of the global interest of human beings, thereby emphasizing the solidarity among human beings prior to articulating private interests.

The challenge ahead is therefore enormous and the dangers are considerable. But there is hope now that the overwhelming task formulated by this article of the Declaration will indeed result in the ousting of dictatorships and the rejection of practices that are degrading for human beings, so that a new humanity will be accomplished that shows solidarity in all its richness and diversity. In this regard, as expressed in the very first paragraph of the Declaration, there is an unwavering belief in the 'unique capacity of human beings to reflect upon their own existence and on their environment, to perceive injustice, to avoid danger, to assume responsibility, to seek co-operation and to exhibit the moral sense that gives expression to ethical principles'.

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Chapter 16

ARTICLE 14: **SOCIAL RESPONSIBILITY AND HEALTH**

Adolfo Martínez-Palomo

Article 14: Social responsibility and health

1. *The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.*
2. *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:*
   a. *access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;*
   b. *access to adequate nutrition and water;*
   c. *improvement of living conditions and the environment;*
   d. *elimination of the marginalization and the exclusion of persons on the basis of any grounds;*
   e. *reduction of poverty and illiteracy.*

BACKGROUND

Global health conditions at the beginning of the new century are marked by growing inequities related mostly to poverty and lack of access to health care services. Health policy has been considered recently to be more than the provision and funding of medical care, by taking into consideration the fact that for the health of the population as a whole, the social and economic conditions that make people ill and in need of medical care are clearly of utmost importance. These include, among others, the lifelong importance of health determinants in early childhood, and the effects of position on the social ladder, poverty, drugs, working conditions, unemployment, social support, adequate food, and transport policy. In contrast, the influence of biological and physical factors on health has been estimated as less than

15 per cent and 10 per cent, respectively (WHO – Commission on Social Determinants of Health, 2007).

It is an accepted fact that more than one billion people – one sixth of the total population of the world – live in extreme poverty, lacking the safe water, proper nutrition, basic health care and social services needed to survive. Poverty is reflected in various aspects of the life of individuals and populations living in deprived conditions in developing countries, but also in some regions of industrialized countries. There is poverty in food, which is scarce in quantity and deficient in quality; there is poverty in housing, which nearly always is inadequate; and there is poverty in knowledge, education and culture. Finally, there is poverty, which approaches real misery that involves the hygiene of persons, houses and the community.

Present global health conditions have been summarized by WHO (2006):

> In this first decade of the 21st century, immense advances in human well-being coexist with extreme deprivation. In global health we are witnessing the benefits of new medicines and technologies. But there are unprecedented reversals. Life expectancies have collapsed in some of the poorest countries to half the level of the richest – attributable to the ravages of HIV/AIDS in parts of sub-Saharan Africa and to more than a dozen 'failed states'. These setbacks have been accompanied by growing fears, in rich and poor countries alike, of new infectious threats such as SARS and avian influenza and 'hidden' behavioural conditions such as mental disorders and domestic violence. The world community has sufficient financial resources and technologies to tackle most of these health challenges; yet today many national health systems are weak, unresponsive, inequitable – even unsafe. What is needed now is political will to implement national plans, together with international co-operation to align resources, harness knowledge and build robust health systems for treating and preventing disease and promoting population health (WHO, 2006: 2).

In addition, recent analyses indicate that the disease burden imposed by neglected tropical diseases has been underestimated. They not only cause approximately 530,000 deaths annually, but also produce much more long-term disability, disfigurement and suffering, resulting in a loss of up to 57 million disability-adjusted life years annually (Hotez *et al.*, 2007).

The guiding principles of most governments have been those of equality of access to health care and solidarity in sharing the financial burden

proportionate to income. However, pressures on health care systems are already imposed by the impact of financial and demographic determinants. These factors were recognized almost 30 years ago in the development of international strategies for health promotion, such as the WHO commitment to a global strategy for Health for All and the principles of primary health care through the 1978 Declaration of Alma Ata. Today, after not being able to reach health for all in the year 2000, health promotion is still a crucial topic of debate.

Subsequent international health policy guidelines have promoted health as a basic human right, essential for social and economic development. It has been considered that health promotion, through investment and action, has a marked impact on the determinants of health so as to create the greatest health gain for people, to contribute significantly to the reduction of inequities in health, to further human rights, and to build social capital. The ultimate goal is to increase health expectancy, and to narrow the gap in health expectancy between countries and groups.

Social responsibilities for health are a fundamental concern for the ethics of professional public health practices. Central concerns are accountability and commitment and the reliable performance of professional tasks in the pursuit of social goods (Weed and McKeown, 2003).

The promotion of social responsibility for health was first established as a priority at the WHO Fourth International Conference on Health Promotion: New Players for a New Era – Leading Health Promotion into the 21st Century, held in Jakarta (WHO, 1997). The conference recommended that decision-makers be firmly committed to social responsibility, and both public and private sectors should promote health by pursuing policies and practices that:

- avoid harming the health of individuals,
- protect the environment and ensure sustainable use of resources,
- restrict production of, and trade in, inherently harmful goods and substances such as tobacco and armaments, as well as discourage unhealthy marketing prices,
- safeguard both the citizen in the marketplace and the individual in the workplace,
- include equity-focused health impact assessments as an integral part of policy development.

The topic of social responsibility for health was further discussed at the WHO Fifth Global Conference on Health Promotion: Bridging the Equity Gap,

held in Mexico City (WHO, 2000). Five broad themes emerged from the discussions among conference participants:

- what constitutes social responsibility for health?
- how do you measure it?
- issues of equity and gender,
- case studies and what they reflect in terms of the prerequisites of success,
- cultural diversity.

It was clear from the participants' discussions that social responsibility, like health, means different things to different people. Defining it becomes particularly important when identifying who is responsible for what. In working together, people need to be clear about rights and responsibilities and need to go through a process of defining social responsibility for health in their own terms, so that there is collective ownership. Some participants felt that governments too often sign up to human rights but fail to follow through and support them at the local levels. However, if social responsibility is devolved, governments too often give up their own responsibilities. A key challenge is to link the different levels of society and develop a dialogue to overcome the inherent tensions. Some participants pointed out that both workplaces and trade unions have a role to play. Trade unions in particular were considered underutilized allies.

More recently, the WHO Sixth Conference on Global Health Promotion, held in Thailand in August 2005, identified in the Bangkok Charter actions commitments and pledges required to address the determinants of health in a globalized world through health promotion (WHO, 2005). Among the key commitments identified was to make the promotion of health a core responsibility of all of government. Thus, it was recommended that governments at all levels must tackle poor health and inequalities as a matter of urgency, because health is a major determinant of socio-economic and political development. Local, regional and national governments must give priority to investments in health, within and outside the health sector, and provide sustainable financing for health promotion. To ensure this, all levels of government should make the health consequences of policies and legislation explicit, using tools such as equity-focused health impact assessment.

EVOLUTION OF THE ARTICLE

The International Bioethics Committee of UNESCO considered that for the improvement of global health conditions, bioethics should address at the

same time the moral values that actually guide the behaviour of individuals and communities and the moral values and priorities that should guide public policies at various levels on these issues. As a consequence, the principle of social responsibility and health was included as one of the important topics of the Universal Declaration on Bioethics and Human Rights.

The First Outline of a Text (June 2004) did not mention this article, nor did the Second Outline (July 2004) or Third Outline (August 2004). The last outline was discussed during the 170th session of the Executive Board of UNESCO (in October 2004). In particular the Latin-American and Caribbean countries expressed the wish that the Declaration cover concrete subjects such as those mentioned in the Second Outline of the Text, for example health care, human reproduction, reproductive human cloning, tissue and organ transplantation. In the fifth meeting of the IBC Drafting Group (October 2004), this issue was underlined by some members who emphasized the social responsibility that derives from bioethics; such responsibility demands that society deals with crucial issues to find solutions based on criteria of equity and justice. They recommended developing examples such as access to health care, clean water and nutrition in the Explanatory Note (IBC Drafting Group, 2004a). This focus on issues of social justice was further advocated in subsequent regional consultation meetings, in particular in the regional meeting in Buenos Aires, Argentina (November 2004). The experts from the region emphasized that bioethics should address concrete aspects of the reality faced by the majority of the world population, such as poverty, hunger, illness, social exclusion, war and violence, and lack of access to health care and medication (Regional meeting Buenos Aires, 2004). The IBC Drafting Group, in its sixth meeting (December 2004), discussed the concerns expressed in the different consultations as to the link between bioethics and global problems such as access to quality health care, nutrition, drinking water, poverty and illiteracy (IBC Drafting Group, 2004b). In order to reflect this concern in the text, the Group decided to introduce a new principle entitled 'Social responsibility', aware of the innovative contribution of the Declaration to this discussion. In the Fourth Outline (December 2004), this new article was formulated as follows:

> **Article 15 – Social responsibility**
>
> Any decision or practice shall ensure, wherever possible, that progress in science and technology contributes in full equality to:
>
> (i) access to quality healthcare, including sexual and reproductive health;

(ii) access to adequate nutrition and water;
(iii) reduction of poverty and illiteracy;
(iv) improvement of living conditions and the environment; and
(v) elimination of the marginalization and the exclusion of persons on the basis of any ground, including gender, age or disability (IBC, 2004).

The draft text of the article gave rise to intensive debate during the joint session of IBC and IGBC in January 2005. This discussion led to some reformulation in the Preliminary Draft Declaration approved by IBC in February 2005. The reformulation introduced the notion of the 'common good'. It also added in (i) 'essential medicines', and removed the reference to sexual health, adding a reference to the health of children:

Article 13 – Social responsibility

Any decision or practice shall ensure that progress in science and technology contributes, wherever possible, to the common good, including the achievement of goals such as:

(i) access to health care and essential medicines, including for reproductive health and the health of children;
(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 (IBC, 2005).

The text of the article was the subject of intense discussion during the second meeting of governmental experts (June 2005). Numerous delegates, particularly representatives of developing countries, reiterated the paramount importance of this article since it reflects the social aspects of bioethics. They expressed the wish that this article also specifically recognize a right to health and affirmed the promotion of health and social development as principles that should be applied by all, in particular by States. On the basis of negotiations, this concern has led to the introduction of paragraph 1 of the article. Although an explicit reference to a right to health was not included, the text of paragraph two referred to the 'enjoyment of the highest attainable standard of health' as 'one of the fundamental rights of every human being'. The relation with health was also underlined by adding this notion to the title of the article. The reference to reproductive health no longer appeared

in the approved formulation; some delegates stated that they regretted this deletion (Report expert meeting, 2005).

In October, 2005 the UNESCO General Conference accepted by acclamation the Universal Declaration on Bioethics and Human Rights, which includes the principle of social responsibility and health.

APPLICATION OF THE ARTICLE

The article on social responsibility and health of the Universal Declaration of Bioethics and Human Rights addresses the fact that the divide between developed and developing countries is continuing to widen in the area of public health, despite remarkable world economic growth and an evident improvement in living conditions thanks to scientific and technological progress. Access to quality health care and essential medicines are taken into consideration, as well as the ethical implications of economic and social policies, and the benefits that investing in health policies can bring. The importance of the social determinants of health is emphasized, as well as its relationship with key aspects of people's living and working circumstances and their lifestyles.

OTHER RECENT INITIATIVES

Further international efforts to meet the needs of the poorest, including better health, have been included in the eight UN Millennium Development Goals (MDG) (UN Millennium Project, 2005). These range from halving extreme poverty to halting the spread of HIV and AIDS and providing universal primary education. The UN concrete action plan to reverse poverty, hunger and disease affecting billions of people was presented in 2005. It was considered that the consequences of poverty reach far beyond the afflicted countries. Poverty, inequality and disease are some of the chief causes of violent conflict, civil war and state failures. Therefore, a world with extreme poverty is a world of insecurity. The Millennium project takes into consideration that the world already has the technology and know-how to solve most of the problems faced in poor countries. The goal is to achieve the following eight goals by the year 2015:

- Eradicate extreme poverty and hunger.
- Achieve universal primary education.
- Promote gender equality and empower women.
- Reduce child mortality.
- Improve maternal health.
- Combat HIV and AIDS, malaria and other diseases.

- Ensure environmental sustainability.
- Develop a global partnership for development.

The UN accepts that there is little time to achieve the goals, because the window of opportunity is closing. A major global policy breakthrough is needed to get the poorest countries on track to meeting the goals. Although critics have claimed that poverty reduction strategies are in essence a collection of development policies that have been tried and have failed in the past, the answer has been that the project is based on addressing simultaneously many needs with a large number of proven, highly effective, low-cost interventions. However, according to many assessments, the world will fail to achieve the Goals by 2015 and, in particular, many countries and regions will fall substantially short of the health targets.

At recent parallel meetings of the Forum 8 organized by the Global Forum for Health Research and the Ministerial Summit on Health Research, held in Mexico City in November, 2004, over 1,400 policy-makers, health ministers, researchers, government representatives, development agencies and research institutions examined the issue of how research could improve strategies and help to attain the MDGs (Global Forum for Health Research, 2005). One of the conclusions of both the Forum and the Summit was that achieving the Goals will require addressing health and its determinants in a comprehensive way and will necessitate further health research of high quality focused on the needs of developing countries and vulnerable populations. It must give systematic attention to cross-cutting issues of poverty and equity, taking account of inequities based on gender, ability, ethnicity and social class, among others; the needs of both the aged and the largest generation ever of young people 0–19 years, and the needs of other specifically disadvantaged groups such as migrants, refugees, and those exposed to violent conflict. It was concluded that all the participants must commit themselves to the shared responsibility of advancing the volume and pace of health research that is focused on improving the lifespan and health of people everywhere. Special consideration was given to increasing funding for health research in systems, research, as it is this activity of research that could contribute most to delivering the already known interventions to improve health.

A specific recommendation on research funding was made at the end of Forum 8, stating that:

> To provide the resources necessary for essential research within developing countries, we urge governments of these countries to spend at least 2% of their national health budgets on health research, as recommended

> by the 1990 Commission on Health Research for Development. These funds should be used locally for health research and research capacity strengthening. Also in line with the Commission recommendation, donors are urged to allocate 5% of their funding for the health sector to health research and research capacity strengthening in developing countries. Monitoring the use of funds for capacity development is a vital complementary activity (Global Forum for Health Research, 2005).

The point here is how governments perceive research. If they see research as an expenditure and not as an investment, the amount of funds will be scarce, mainly when the funds in poor countries have to be distributed among greater needs, relegating health research as an expenditure and an activity that is not a priority. This will lead to a vicious cycle that will not make it possible to improve the social determinants of health. But also, we come to a basic question: Is there a key determinant to development that is more important than health?

Development agencies have challenged the pharmaceutical industry to improve its efforts to tackle the health crisis affecting developing countries. They consider that a socially responsible company should have policies on access to treatment for developing countries which include the five priorities of pricing, patent, joint public-private initiatives, research and development, and the appropriate use of drugs. They comment, in addition, that the industry currently defines its policy on access largely in terms of philanthropic ventures, and that critical challenges remain, particularly the issue of pricing.

Pharmaceutical companies are commercial enterprises almost exclusively focused on generating maximal returns for their shareholders. Recently, however, new projects have a distinctly charitable aspect and will not generate profits. Examples include the new Institute for Tropical Diseases in Singapore for the discovery of drugs for tuberculosis and dengue, and a considerable number of projects aimed at new treatments for malaria, elephantiasis, river blindness, HIV and AIDS, leprosy, dengue, and sleeping sickness (Herrling, 2006).

A number of alliances with public, private, NGOs, international organizations and civil society have been organized with the aim to address the determinants of health in a globalized world through health promotion. Two recent alliances are described below.

The Grand Challenges in Global Health initiative is a partnership dedicated to supporting scientific and technical research to solve critical health problems in the developing world. The initiative's partners are the Bill & Melinda Gates Foundation, the Canadian Institutes of Health Research, the Foundation for the National Institutes of Health, and the Welcome Trust.

A grand challenge is to direct investigators to a specific scientific or technical breakthrough that would be expected to overcome one or more bottlenecks in an imagined path towards a solution to one, preferably several, significant health problems. Therefore a grand challenge is envisioned as distinct from a simple statement of one of the major problems in global health, such as malnutrition or lack of access to medical care. The initiative has identified and supported seven long-term goals to improve health in the developing world:

- to improve childhood vaccines,
- to create new vaccines,
- to control insects that transmit agents of disease,
- to improve nutrition to promote health,
- to improve drug treatment of infectious diseases,
- to cure latent and chronic infection,
- to measure health status accurately and economically.

The Reaching the Poor Program (RPP) is an effort to begin finding better ways of ensuring that the benefits of health, nutrition, and population (HNP) programmes flow to disadvantaged population groups. It has been undertaken by the World Bank, in co-operation with the Gates Foundation and the Dutch and Swedish Governments. In order to help improve how well HNP programmes reach poor people, the RPP seeks to:

- Determine which HNP programmes do and do not reach disadvantaged groups effectively. The resulting information, produced through application of recently-developed quantitative techniques for assessing programmes' distributional performance, is intended to provide guidance to policy-makers about which approaches to adopt and to avoid in developing pro-poor initiatives;
- Encourage others to undertake similar determinations of HNP programme effectiveness in reaching the poor. More widespread application of the techniques just mentioned, derived from the 'benefit incidence' approach used to determine who benefits most from government expenditures, would allow policy-makers to assess and then improve their performance in reaching the poor on an ongoing basis.

The programme considers that health policies do not have to be inequitable: 'While most health, nutrition, and population services exacerbate poor-rich inequalities by achieving much lower coverage among disadvantaged than among the better-off, many significant and instructive exceptions exist. These demonstrate the feasibility of reaching the poor much more effectively than at present, and point to promising strategies for doing so'.

CONCLUSION

In conclusion, the widening gaps in health conditions described above are best explained in terms of social, economic and cultural differences and the value that individuals and societies attribute to the idea of a healthy society. Therefore, individual responsibility and social responsibility are usually inextricably intertwined and are related to moral judgments and political strategies that may or may not seek equity as a goal.

Health is everyone's responsibility: the public and private sectors, governments of developed and developing countries, NGOs, multilateral agencies and civil societies, and, obviously, individuals.

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Chapter 17

ARTICLE 15: **SHARING OF BENEFITS**

Hans Galjaard

Article 15 – Sharing of benefits

1. *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:*
   a. *special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;*
   b. *access to quality health care;*
   c. *provision of new diagnostic and therapeutic modalities or products stemming from research;*
   d. *support for health services;*
   e. *access to scientific and technological knowledge;*
   f. *capacity-building facilities for research purposes; and*
   g. *other forms of benefit consistent with the principles set out in this Declaration.*
2. *Benefits should not constitute improper inducements to participate in research.*

INTRODUCTION

Sharing of benefits is the title of Article 15 of the Universal Declaration on Bioethics and Human Rights, which has been unanimously adopted by the General Conference of UNESCO in October 2005. It seems more relevant than ever to pay attention to this principle, which for thousands of years forms part of the Holy writings of the major world religions. Apparently this principle has not sufficiently been followed given the impressive inequalities that exist in the world today.

Article 15 focuses on benefits from scientific research and its applications and mentions, among others, access to quality health care and

to scientific and technological knowledge and capacity-building facilities for research as possible forms of benefit, in particular to persons and populations in developing countries.

During the preparation of the Declaration it became clear that in most wealthy countries of the world in the debate about bioethics, priority is given to individuals, whereas in many developing countries the emphasis is more on families, clans, ethnic groups, and sometimes on society as a whole. Such differences in perception have of course also an influence on the desired practice of sharing benefits. As in dealing with several other bioethics issues, it may well be that the realization of this important principle requires a pluralistic approach.

THE EVOLUTION OF THE ARTICLE

Already in the first meeting of the Drafting Group of the International Bioethics Committee in April 2004, reference was made to benefit-sharing as one of the general principles that should be included in the future Declaration (IBC Drafting Group 2004). In the First Outline of a Text (IBC, 2004a), benefit-sharing was mentioned as an application of the general principles. In the Second Outline of a Text, benefit-sharing was included in the section on implications of the general principles (IBC, 2004b). An elaborated text appeared for the first time in the Third Outline of a Text (IBC, 2004c) as one of the 'derived principles':

> **Article 13 – Sharing of benefits**
>
> In accordance with international and domestic law, benefits resulting from scientific research and their applications should be shared with the society as a whole and the international community. In giving effect to this principle, benefits may take any of the following forms:
>
> (i) special assistance to the persons and groups that have taken part in the research;
> (ii) access to medical care;
> (iii) provision of new diagnostics, facilities for new treatments or drugs stemming from the research;
> (iv) support for health services;
> (v) access to scientific and technological knowledge, in particular for developing countries;
> (vi) capacity-building facilities for research purposes;
> (vii) any other form consistent with the principles set out in this Declaration.

The text of the article was primarily based on Article 19 of the International Declaration on Human Genetic Data. Given the complexity and sensitive nature of the issue, the IBC Drafting Group wanted to retain the formulation as agreed upon earlier by the Member States, inserting examples such as access to technological and scientific knowledge, and by generalizing the text beyond the focus on genetic data. The text of the draft article remained in the Fourth Outline of December 2004 (IBC, 2004d), although some minor changes were made. The reference to developing countries, for example, was no longer included in (v) but moved to the general first part of the article. Furthermore a second part was added:

> b) This provision may be implemented through legislation, international agreements or by other appropriate means, which shall be consistent in every case with international human rights law.

The Preliminary Draft Declaration, issued by the IBC a few months later in February 2005, presents the text as it is in the finally adopted Declaration. Only one change has been made compared to the previous Fourth Outline. In the first part (a) of the article under (i) instead of 'special assistance' the wording 'special and sustainable assistance' has been introduced (IBC, 2005).

The final text of the article adopted by the IBC was subjected to minor changes by the governmental experts in their second meeting in June 2005. In the text of first part of the article under (a) (previously i) was added 'and acknowledgement of'. In the first part under (c), 'facilities for new treatments or medical products' was changed to 'therapeutic modalities or products'. The most important change, however, was the deletion of the second part and its replacement with an entirely different formulation: 'Benefits should not constitute improper inducements to participate in research' (Report expert meeting, 2005). The text adopted by the governmental experts was subsequently adopted by the General Conference therefore became part of the final Declaration.

EXISTING INEQUALITIES

The data provided by international organizations like UNDP/UNFPA, WHO and the World Bank illustrate enormous inequalities among the world's countries (see Table 1). This concerns economic strength, the availability of clean water, sanitation, adequate shelter and nutrition, and access to education and health care. Also, gender inequality, in many parts of the world culturally determined, has a negative effect on literacy, education, unwanted pregnancy, maternal and child mortality, and hence on future development.

Table 1: Differences in the world

	Least developed countries	Less developed countries	Well developed countries
GNP per capita (US$)	1,524	5, 430	26,395
Infant mortality	94	60	7
Life expectancy (yr)	51	64	76
Maternal mortality (per 100,000 births)	950	202	8
Fertility rate	5.1	2.9	1.6
Births per 1,000 women 15-19 yrs	119	61	26
Female adult illiteracy (%)	62	18	0

Source: Human Development Report, 2005.

If the sharing of benefits is to be taken seriously, a first priority is the realization of an optimal life expectancy for all newborns. At present there are extremes of an average life expectancy of more than 80 years in some high-income countries and of 30 years in some of the poorest African countries. Also the fact that nearly half of the overall mortality in poor countries is preventable (nutrition, mother and child care, vaccination, medicines) is unacceptable.

A second basis of optimal development of individuals and societies is education and training. Again, the data show that there is much to do in that area. Between 1960 and 2000, the percentage of children attending primary school increased from 48 to 82 per cent, which is encouraging and illustrates that important goals can be achieved. Nevertheless, worldwide 300 million children have no access to education, two thirds of whom are girls. A large proportion of them are engaged in paid labour, often in very poor conditions.

Worldwide 500 million women are illiterate and 280 million men. The gender gap widens at the secondary school level, which is especially sad since it is known that secondary education yields high returns for women, like avoiding teenage pregnancy, increased use of maternal health and family planning services, and a better understanding of harmful practices and dangers posed by infectious diseases like HIV. It seems mandatory to invest in the health and education of the 1.2 billion adolescents (10-19 yrs), the majority of whom live in poor countries; hopefully in the future they will be equal partners of their contemporaries in high-income countries.

APPLICATION OF THE ARTICLE

When the principles expressed in Article 15 are applied in practice, it will have important implications for several areas of health care.

Mother and child care

The encouraging fact is that during the period 1960 to 1990 the global infant mortality has reduced by 50 per cent. The negative news is that 14 million children still die annually, mostly in developing countries, which implies that every day 38,000 children do not have any chance of living. The majority of this infant mortality is due to a combination of malnutrition and infectious diseases, but also prenatal and perinatal complications, as well as congenital anomalies and genetic diseases.

Whereas in the wealthy countries more than 99 per cent of the liveborns reach adult age in several African countries, 10–16 per cent of the liveborns die during their first year of life. Sharing of benefits should aim at the reduction of this large gap. Clean water, safe shelter, adequate nutrition, timely vaccination and access to health care and essential medicines are prerequisites.

More indirectly, a 5–10 per cent reduction of the under-five year-old child mortality rate can be achieved by each year of education provided to mothers. As was mentioned earlier, secondary education of girls also contributes to a better uptake of health care and family planning services. Although the world's fertility rate is decreasing gradually, the figures for (illegal) abortion and maternal mortality in low-income countries are alarming. An estimated 76 million unplanned pregnancies occur in the developing world annually. Since in many countries in Latin America, Asia and Africa there are no opportunities available, about 20 million abortions are performed illegally, often with fatal results or chronic complications. Of the continuing pregnancies, only half of the deliveries are attended by trained personnel. Altogether the maternal mortality in the poorest countries is more than 100 times higher than in the high-income countries. In the developing world, every minute a woman dies as a result of (unplanned) pregnancy.

Together with a reduction of child mortality, better chances for women should be a priority in future efforts of benefit sharing. Better chances also imply avoidance of violence (now one in three women are victims of violence/sexual assault) and require optimal information of teenagers about reproductive issues and equal rights of men and women. According to the Human Development Report (UN, 2005), the goals of the UN Millennium project to halve poverty and starvation by 2015 can only be realized if equal

rights and care for women of reproductive age are at the top of the political agenda (see also Article 10 of the Universal Declaration on Bioethics and Human Rights).

Health care facilities

The major determinant of life expectancy at birth is the rate of infant mortality. In the high-income countries during the past century, the major reduction in child mortality has been due to improved socio-economic factors and hygienic conditions, followed by vaccination programmes and the availability of antibiotics. As has been mentioned earlier, we have not sufficiently shared those essential conditions among the various populations of the world.

Although the contribution of modern health technology has often been questioned, the infant mortality in wealthy countries has decreased by a factor of 10 since the Second World War. This reduction is associated with improved prenatal and perinatal care, more sophisticated methods of early diagnosis of structural and functional abnormalities, improved surgical methods and new vaccines and medicines.

It is also worth mentioning that the quality of life in (advanced) adulthood has significantly improved for people, populations and countries who can afford modern health technology. Diagnostic methods have evolved from radiology to ultrasound and nuclear magnetic resonance, from electrocardiography to fiber optics, and from clinical chemistry to chromosome and DNA analysis. Curative methods have also improved, though relatively to a lesser extent: new antibiotics and analgetics, antidepressive medicines, anti-immunological drugs, radio- and chemotherapy, improved surgery including transplantation of tissues, organs and artificial materials. Millions of people in wealthy countries have benefited from modern cardiology and cardiosurgery, artificial hips and knees, and correction of visual impairments. At a smaller scale, prenatal diagnosis and artificial reproductive methods have been valuable for parents at increased risk of conceiving a handicapped child and for infertile couples. Some of these technical developments have also raised ethical concerns which have been dealt with both nationally and internationally, including by UNESCO; see the Universal Declaration on the Human Genome and Human Rights (1997) and the IBC reports on the Use of Embryonic Stem Cells in Therapeutic Research (IBC, 2001) and on Pre-implantation Genetic Diagnosis and Germ-line Intervention (IBC, 2003) and various reports by WHO and the Nuffield Council on Bioethics.

The development and application of modern health technologies have also had a socio-economic price. In the Netherlands, the number

of professionals working in health care has grown from 100,000 in 1960 to about 1 million in 2005. The costs have increased 40 fold in absolute amounts and twofold as a percentage of GNP to about 9 per cent. In the USA this percentage has reached 15 per cent of the GNP. Unfortunately some 45 million Americans are not or are under-insured, so the need for sharing benefits is not restricted to developing countries.

How far can and should the sharing of benefits be evaluated if the UNESCO Declaration's recommendations in Article 16 'access to quality health care' and 'provision of new diagnostic and therapeutic modalities or products stemming for research' are to be followed? There is no uniform answer to this question.

The economic strength of a population, the existing infrastructure including trained personnel at various levels, and the cultural perception of life, disease and death all play a role. A matter of great concern for the future is the emigration of medical doctors, nurses and scientists from low-income countries to centers in the wealthy world. In recent years China has succeeded in getting back experts by giving them high salaries and by creating good instrumental facilities, which allows the returning experts to continue their work at a competitive level.

Another obstacle in realizing access to high quality health care is the patenting and extremely high costs for pharmaceutical companies to develop new medicines. The average cost of a new successful medicine is between US$500–1,000 million and it takes 10–12 years after patenting before it is on the market. The high costs are due to the fact that only a small proportion of new medicines are cost-effective, the strict regulations that have to be followed during the testing and the difficulties of performing clinical trials. Altogether this makes the bulk of new medicines inaccessible for the citizens of low-income countries. International patent law and the World Trade Organization (WTO) regulations make it difficult or impossible for a developing country to produce its own medicines, although in recent years some promising progress has been made in licensing by pharmaceutical companies and by the production of generic medicines. Yet, the fact that in several African countries less than 10 per cent of HIV and AIDS patients receive protease inhibitors illustrates that there are great challenges ahead.

With the statement by governments in the USA and Europe that patients with rare diseases have equal rights to optimal treatment as patients with more common diseases, the problem of high costs of medicines becomes relevant also in wealthy countries. For some rare genetic diseases, protein replacement therapies have been developed which are lifelong treatments that cost between

US$150,000–200,000 per year per patient. This poses the ethical issue of comparison with other forms of care, which could be provided for the same money to thousands of other people especially in poor countries. It also emphasizes the tension between the interest of the individual and that of society.

Research

Prerequisites for successful research are optimal education and training, modern instrumental facilities, opportunities for international communication and sufficient financial means to maintain and extend the infrastructure.

If scientific breakthroughs, Nobel prizes, top cited publications and patents are used as criteria, only a few countries like the USA, Japan, Great Britain and some other European countries are and will be successful in research. It is, however, generally accepted that important new developments both in concepts and technology rest on a broad basis of less striking research. Also, any country will only be able to apply new developments elsewhere when it has a minimum of owned infrastructure in basic science and applications. This is also mandatory for the motivation, education and training of a country's own professionals. Sharing of benefits can only be realized if national/regional professionals are available as partners in international collaboration. There are several examples of low-income countries, which have given priority to education, training and research facilities.

Research today is both competitive and collaborative, especially in medical biology. Since the completion of the human gene map, international efforts are aimed at the identification of the combinations of genetic and environmental factors responsible for major multi-factorial disorders like cardiovascular disease, cancer, and psychiatric and neurodegenerative disorders. Also the pharmaceutical industry has high expectations for the development of new medicines that are targeted to specific molecular mechanisms, which are disturbed in disease.

For this purpose it is fruitful to investigate DNA sequences in isolated populations, and unfortunately this has not always been conducted in an ethically correct manner. Illiterate groups of people living in remote areas have been approached for so-called medical examination, whereas the only purpose was to obtain some of their cell/DNA material. This has led the Chinese molecular biologist Yang Huanming to the statement: 'Please act in China as in your own country' (Yang, 2001).

In many countries there is not yet an organization of bioethics committees, nor are there local, regional or national regulations to ensure that

the principles set out in the Universal Declaration on Bioethics and Human Rights are adhered to. Here, sharing of benefits can be realized by collaboration with experts from countries which already have a sufficient infrastructure for bioethical trial. UNESCO has set up a collaborative project between experts from wealthy and low-income countries to implement this.

Another essential part of scientific research is information. For professionals and leaders of institutes in developing countries it is not easy to travel around the world to gain insight into the situation. The modern information and communication techniques have greatly facilitated exchange of information, but have so far mainly been to the advantage of professionals in wealthy countries.

Sharing of benefit might involve a different approach towards copyright and financial requirements, thereby enabling better access to scientific and technological knowledge by professionals in developing countries, as is recommended in Article 15 of the Declaration.

In order to contribute to medical biological research, experts in developing countries do not necessarily need to dispose of all sophisticated technology that exists. Networks of collaboration would enable a division of labour with a role for experts in developing countries at the clinical and epidemiological level. In the era of population genomics, professionals in developing countries may play an important role in collecting relevant material from well-defined populations and have this analyzed by well-equipped laboratories in wealthy countries.

This requires, of course, well-established networks of international collaboration, trust and acknowledgement of those involved in the research. Also the ethical principles set out in the Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003) and the Universal Declaration on Bioethics and Human Rights (2005) have to be taken into account in these types of international collaboration.

Presently some US$80 billion is spent globally on health research and development. Only 10 per cent of this is devoted to the 90 per cent of the world's disease burden. An important contribution to the principle of sharing benefits would be if scientists in the wealthy world redirected some of their research aims towards the major problems of the poorer countries. Again, this might be done through collaboration between countries and, in some instances, with the support of international organizations.

An important and not yet resolved issue is the sharing of benefits with lay people who have collaborated in population studies or in clinical trials. In an

increasing number of wealthy countries, scientists and health authorities have started large-scale population studies (up to 500,000 in the United Kingdom) aimed at identifying disease-causing factors. The epidemiological set-up, the necessary DNA micro-array technology and the computer facilities have been well planned. However, the feedback to individual participants, if any, has not received sufficient attention. The same is true for participants in low-income countries, where often the contact with (foreign) experts is broken as soon as the required material has been collected. More experience and, in some instances, strict protocols exist for clinical trials of new vaccines or medicines, and it might be useful in population genomics to learn from these experiences.

CONCLUSION

During the discussions associated with the drafting of the Universal Declaration on Bioethics and Human Rights, but also during other debates on bioethics issues, concern has been expressed about the fact that the rapid developments in information technology and biotechnology will increase the gap between the wealthy countries and the developing world. Article 15 was meant to diminish existing inequalities to prevent a broadening of the gap and to build a basis for future international collaboration where professionals from various backgrounds play an equivalent role. Finally Article 15 was meant to protect people who are insufficiently informed from improper participation in research projects or clinical trials. People who take part in such projects should share the benefits which may arise from these.

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Chapter 18

ARTICLE 16: **PROTECTING FUTURE GENERATIONS**

Takayuki Morisaki

Article 16 – Protecting future generations

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

WHY IS THIS ARTICLE IN THE DECLARATION?

Although this Article was not included in the draft when the IBC finalized it in February 2005, the Intergovernmental Meeting of Experts decided to add a new article concerning the protection of future generations. This is because the Preliminary Draft Declaration mentioned this concept only in the section on aims, but did not mention it in a particular article. Therefore, the independent article regarding this was reflected in the final version. Of course, the concept of this Article was indeed reflected in the original draft by the IBC in Article 3(vii) (Aims) as:

> The aims of this Declaration are: to safeguard and promote the interests of the present and future generations.

The mention of future generations was included at the very beginning of the drafting process. Therefore, we can say that it has been, since the start of the drafting process, one of the backbone ideas of the Declaration.

WHAT DOES THE ARTICLE MEAN?

There was no questioning during the process of elaboration and negotiation why this Article should be included in the Declaration. Therefore, during the drafting process and the discussions of various draft texts, there has been consensus that bioethical issues should be considered not only for the present generation but also for future generations. This Article is also closely connected with another normative instrument adopted by UNESCO in 1997,

that is the Declaration on the Responsibilities of the Present Generations towards Future Generations. This Declaration underlines the relationship between humankind, life on earth, environment and biodiversity (UNESCO, 1997). Article 17 of the Universal Declaration on Bioethics and Human Rights mentions responsibility towards the biosphere. This responsibility should extend to future generations and the actual decisions taken should keep that in mind. This shows the importance of having included future generations in Article 16. Agius (2006) has argued that it is important that the international community has recognized in international documents, treaties and conventions the concept of our moral responsibilities to future generations. This implies that the concept of intergenerational justice is now at the fore of today's international environmental concerns. But the principle of protecting future generations has a much wider scope: it is important for the future of humanity. Agius (2006) explains that it demonstrates that a broader notion of humanity is at work here: 'humanity' is not only the international community, including all people living today, but it refers to the chain of generations who collectively form one community, whether living now or in the future (Agius, 2006).

HOW CAN THE ARTICLE BE APPLIED?

The article on protecting future generations will be potentially useful when a decision has to be made regarding procedures based on the rapid progress of new technologies. In such circumstances, the development of life science and technology is expected to contribute to the improvement of our lives through better diagnosis or new therapies. For example, human genome information will provide not only accurate, personalized or individual diagnosis, but also a better choice of therapeutic procedures. However, such new technology may result in undesired outcomes for the next generation. For example, some particular therapeutic procedure based on a specific (individual) genetic character might cause unexpected and undesirable outcomes in the future descendent of the individual, as in the case of gene therapy targeting germ line cells. Therefore, the bioethical decision-making process should not only take into account the impact on the present generation, but also try to evaluate the impacts on future generations. Such considerations have become more important in the application of the rapidly progressing development of new technologies like genomic science or stem cell biology. In this context, scientists coming from the health arena should not be the only ones involved in the decision-making process; social scientists or lay persons should also

be called upon to make a contribution. Therefore, bioethics committees at the national and regional levels as well as the institutional level have to play an important role in the decision-making process. Also, other types of national, regional or institutional bodies might be needed to discuss such issues. Multidisciplinary discussions and international co-operation, including UNESCO activity, will help us to reach better decisions on those complex topics.

This article indicates that we have to consider not only ourselves but also our global community and members of future generations.

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Chapter 19

ARTICLE 17: **PROTECTION OF THE ENVIRONMENT, THE BIOSPHERE AND BIODIVERSITY**

P. N. Tandon

Article 17: Protection of the environment, the biosphere and biodiversity

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

BACKGROUND

Bioethics is a discipline that covers the ethical, legal, social and cultural dimensions of life sciences and the technologies which are associated with them. It is concerned with the moral relevance of human intervention in relation to life. In its broadest sense it is concerned with all life forms: plants, animals including humans, and the diverse ecosystems. The inescapable fact is that the introduction of new technologies necessary for development brings with it irreversible social, ecological and health consequences, which under certain circumstances can be harmful. They must be anticipated, recognized, prevented and mitigated if we are to avoid disaster of the kind most developing and developed countries are facing today.

As stated in the Preamble of the Universal Declaration, 'Aware that human beings are an integral part of the biosphere, with an important role in protecting one another and other forms of life, in particular animals', it is expected that the Universal Declaration on Bioethics and Human Rights would reflect upon the entirety of this field. However, owing to the time available for our deliberations, the work done by other agencies and the expertise developed over the years by the IBC, the major emphasis of this Declaration was in respect to human beings who have 'the unique capacity to reflect upon their own existence and on their environment, to perceive injustice, to avoid danger, to assume responsibility, to seek cooperation and to exhibit the moral sense that gives expression to ethical principles'.

During the first meeting of the IBC Drafting Group for Elaboration of a Declaration on Universal Norms on Bioethics, held in Paris on 30 April 2004, it was observed that:

> While recognizing that the human being is an element of biodiversity and as such his/her well-being and development are closely linked to the ecosystem in which he/she lives, some members drew attention to a risk of conflict of competence with other organizations of the United Nations system, as well as with the feasibility studies in progress for the elaboration of guidelines on subjects such as the environment in the framework of UNESCO's programme of ethics of science and technology.
>
> Given the time limit imposed by the General Conference of UNESCO, the Drafting Group therefore decided to concentrate in the first place on the human beings, while leaving open the possibility, if necessary, to refer to other fields and /or to cover them in the future (IBC Drafting Group, 2004a: para. 10 and 11).

In discussions about the principles to be included in the Declaration, during the second meeting of the Drafting Group, the above was reiterated:

> While confirming the choice to concentrate in the first place on the human being, the Group wished to see reflected in the text the fact that the human being, as an integral part of the biosphere, has responsibilities and obligations towards all other forms of life. This should be affirmed as a general principle, thus recognizing with force as a starting point the interrelation between the human being and his ecological environment. Furthermore, so that it be understood that the action of IBC, and to a larger extent UNESCO, is not limited to the human beings, it appeared important to recall the various activities carried out by the Organization in the field of natural, social and human sciences, particularly the feasibility studies within the frameworks of the work of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) of an international instrument on ethics of the environment as well as the activities developed for example within the UNESCO programme of Man and the Biosphere (MAB) (IBC Drafting Group, 2004b: para. 9).

The group was conscious of the larger role of UNESCO in this respect as reflected in the work of the World Commission on the Ethics of Scientific

Knowledge (COMEST) and the Man and the Biosphere Programme (MAB).

Keeping this in mind and notwithstanding the primary focus on human beings, the Declaration repeatedly refers to our concerns for the environment, biosphere and biodiversity as is obvious from the following. Article 1 (Scope) of the Declaration states that it addresses ethical issues as applied to human beings, 'taking into account their social, legal and environmental dimensions'. Article 2 (Aims) emphasizes that it aims to safeguard and promote the 'interests of the present and future generations'. It further underlines the importance of 'biodiversity and its conservation as a common concern of humankind'. Article 14 (Social responsibility and health) mentions as one of the determinants that should be advanced by progress in science and technology: 'improvement of living conditions and the environment'. Finally Article 16 is devoted to protecting future generations.

EXPLANATION OF THE ARTICLE

This concern with environmental issues, already expressed in preceding articles, is then explicitly enunciated in Article 17. The Declaration was based on the recognition that the future of humanity will be radically based on technology, and the twenty-first century will be the age of biology. The growing power of biosciences has already provided us with tools and technologies to diagnose, prevent and treat a variety of human diseases. It holds immense potential for solving the persistent predicaments of humanity – poverty, hunger, malnutrition, environmental degradation, shortage of fresh water, insufficient land on which to grow food, diseases without any known cure and unabated risks of global epidemics. It is the wide scope and all-pervasive nature of the applications of the biosciences, including biotechnology, that hold immense potential for dealing with these curses of humanity. These, in addition, have direct or indirect consequences for the whole ecosystem. At the same time these advances have empowered us to change the very nature of our species, if scientists were authorized to pursue their work unconcerned with ethical and moral concerns. While utilizing the current and future advances in bioscience for the benefit of human beings, Article 17 would remind us that, even when we promote human rights, the protection of the whole ecosystem, the biosphere and its biodiversity should not be forgotten. This would ensure their ethical application and at the same time enhance human values.

During the deliberations of the IBC, it was repeatedly emphasized that the Universal Declaration on Bioethics and Human Rights, while retaining a

primary focus on human beings (for reasons elaborated below), meant that any decision or practice within the scope of this Declaration shall have due regard for their impact on all forms of life, recognizing the special responsibility which rests on human beings to protect biodiversity and the biosphere within which human beings exist.

It is in this light that this article is further elaborated in respect to the environment, the biosphere and biodiversity. The earth system consists of physical and biotic components, which have evolved together in continuous interaction towards its present state of complexity. Over the past few decades scientific work has established that human activities have caused abrupt and unprecedented modifications in the planetary life-support system.

The component parts of the earth system are the atmosphere, the marine and the terrestrial compartments. These are connected by fluxes of matter, that is the hydrological and the biogeochemical cycles. The earth system is, in principle, one and indivisible, because all parts are interconnected by delicate control mechanisms operating on various space and time scales (ICSU, 1992: 127–128).

> The earth's linked physical and biological systems – the atmosphere, oceans, soils, minerals, fresh water, and living organisms – keep the planet fit for life and, able to provide for most human needs. The World's ecosystems and the species in them, in addition to their intrinsic value, provide many goods and services needed to sustain human life …They also recycle and purify water, mitigate floods, pollinate crops and cleanse the atmosphere. Humanity now can change the environment on a global scale, as it has with the composition of Earth's atmosphere and may be doing with its climate (World Scientific Academies, 2000: 4).

It is in the interest of humanity and human health to safeguard the welfare of the biological species and their ecosystems, since the state of the environment is a major determinant of health, and good health is a fundamental human right:

> The introduction of new technologies often leads to major transformation in the local environment. Such efforts often create new health risks for local populations... However the long term health effects of the associated environmental contamination are seldom considered in the planning process for such activities (IDRC, 1992: 3).

Article 17 of the Universal Declaration on Bioethics and Human Rights also includes concern for biodiversity in addition to the environment and

the biosphere. The US Congressional Office of Technology Assessment defined biodiversity as follows: 'Biological diversity refers to the variety and variability among living organisms and the ecological complexes in which they occur' (OTA, 1987). Biological diversity is a term used to encompass different ecosystems, species, genes and their relative abundance (ICSU, 1992: 207).

It has long been recognized that the conservation of biodiversity can benefit human health. A wide range of pharmaceuticals are derived from the raw material found in nature; the world's major food crops depend on new genetic material from the wild to remain productive, and intact ecosystems that harbour biodiversity play an important role (Mogelgaard, 2003).

APPLICATION OF THE ARTICLE

The relationship between the human being and the environment changed markedly with the advent of the industrial revolution, the development of the chemical industry and the introduction of nuclear technology. Recent advances in molecular biology, recombinant technology, genetics and biotechnology in turn call for a vigilant public system to monitor and prevent their adverse effects on the environment. No doubt adequate use of biotechnology can be of great benefit to the society by producing new drugs, reagents, diagnostics kits, vaccines, engineered plants and genetically modified food.

Scientific disciplines such as biology, sociology and economics show us that our evolution involves not only competition for survival of the fittest, but a high degree of collaboration (symbiosis) for the survival of the global living system. The development of new technologies must therefore respect local and national social, cultural and environmental constraints, and should pose no risk of irreversible damage.

In this globalizing world it is important to be aware of the environmental costs of our endeavours in science and technology, since the recent advances, especially in biological sciences (be it the genetically modified organisms (GMOs) or genetically engineered organisms, which can influence the health of human beings, animals and crops), can have far-reaching impacts on our ecosystem, not only locally but also globally.

Contrary to the belief perpetuated by the nineteenth century scientific revolution which promoted the idea that 'scientific knowledge could be used to render ourselves masters and possessors of nature' (UN, 1992), prudence dictates that advances in science and technology should not be viewed and utilized only for the benefit of humankind, but the whole ecosystem, since

the former is an integral part of the latter. It has been wisely observed that, 'We are managers but not the owners of biosphere. Hence it is our moral and ethical responsibility to protect it and preserve it for its sustainable utilization to meet the current needs and those of the future generations' (UN, 1992).

Other United Nations bodies have expressed similar sentiments. They have pointed out in fact three important ideas: (1) Human beings depend on the earth to sustain life; (2) There are linkages between human activity and environmental issues; and (3) Global concerns require local actions. For example, the Johannesburg Summit reiterated the concerns about the environment, ecology, the world climate change in the context of the emerging global development patterns, technological changes, life styles, and consumption patterns (UNEP, 2002). The UN/IAS Project on Global Ethos has called attention to the fact that whether or not the twenty-first century achieves a safe, just, humane and inhabitable environment for all depends, to a large degree, on the success or failure to undertake globally concerted actions that would lead to solving pressing global problems.

In this regard it will not be out of place to quote some excerpts from a statement by the Interacademy Panel of the World Academies of Science in May 2000:

> Scientific knowledge has led to remarkable advances that have been of great benefit to humankind … At the same time the applications of scientific advances have led to environmental degradation … contributed to social imbalance … Global trends in climate change, environmental deterioration, and economic disparities are growing concerns (UNESCO, 1999).
>
> The earth's linked physical and biological systems – the atmosphere, oceans, soil, minerals, fresh water, and living organisms – keep the planet fit for life and able to provide for most human needs...
>
> Achieving a transition to sustainability will require safeguarding the welfare of biological species and their ecosystems in a rapidly developing world, even as we improve our still modest scientific understanding of their complex ecological processes (World Scientific Academies, 2000: 4).
>
> It is generally recognized that there is unmistakable evidence that the carrying capacity of our planet is already showing signs of distress (Tandon, 2000).

Safeguarding the capacity of ecosystems must go hand in hand with the improvement of living standards and the promotion of human development (and the introduction of any advances of science and technology for this purpose).

The fact that ecosystems form the precondition for long-term human welfare would require that planning and economic development of industrial and other enterprises should take into consideration the environmental cost of such activities. Thus, while evaluating the ethical implications of any biological research or biotechnology, it is imperative to take into account not only its utility for human welfare, but also its overall impact on our ecosystem. Safe development of these activities implies in the first place the development and application of standardized norms and procedures, use of good laboratory (GLP) and manufacturing (GMP) practices to ensure biosafety. Many developing countries still have not formulated appropriate legal instruments to deal with this subject. The lack of such legislation can expose a nation to misuse of its territory for experimental activities considered unlawful in countries where biotechnology is legally controlled.

It is therefore necessary to establish, if possible through national legislation (and/or international agreements), safety norms and control mechanisms for the use of genetic engineering techniques in the construction, cultivation, manipulation, transport, commercialization, consumption and disposal of GMOs, aiming to preserve the life and health of humans, animals, plants and the environment.

States, nations and international agencies (such as WHO, UNESCO and UNEP) have to play an active and fundamental role in this process through the control of all biotechnological activities involving any risk to agriculture, nutrition, human and animal health while protecting the environment. Environmental security is no longer peripheral to the issues of human health, food and nutritional security. It is an integral part of it and neglecting it yesterday has proved costly today, and could prove far costlier tomorrow.

It has been well recognized that no valid socio-economic or technological paradigm can be built unless man's relationship with the ecosystem and the universe is properly understood and cared for. This holistic paradigm demands a technology with a human face, used as an instrument to serve both humankind and nature. The world needs to manage itself as a system.

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Chapter 20

ARTICLE 18: **DECISION-MAKING AND ADDRESSING BIOETHICAL ISSUES**

M.A. Hamdan

Article 18 – Decision-making and addressing bioethical issues

1. *Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.*
2. *Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.*
3. *Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.*

SIGNIFICANCE OF THE ARTICLE

Professionalism, honesty, integrity and transparency are basic ethical values that should be promoted in every decision or practice related to medicine, life sciences and associated technologies. Hence, Article 18 may be considered significantly relevant to each of the principles set forth in this Declaration.

The ethical principles embodied in Article 18 relate directly to a number of the aims of the Declaration as expressed in Article 2, namely (relevant phrases are in italics):

> Aim (ii) *To guide the actions* of individuals, groups, communities, institutions and corporations, public and private.
>
> Aim (iv) To recognize the importance of freedom of scientific research … while stressing the need *that such research* and developments *occur within the framework of ethical principles set out in this Declaration* …
>
> Aim (v) To foster multidisciplinary and *pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole.*

> Aim (vi) To promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the *rapid sharing of knowledge*...

EVOLUTION OF THE ARTICLE

The text of Article 18 is the result of a sequence of several substantial as well as editorial proposals and modifications. These proposals and modifications will be described briefly in the following paragraphs in comparison with only the last two pre-final versions of the Declaration, namely, the Fourth Outline of a Text of 15 December, 2004 (IBC, 2004), and the Preliminary Draft Declaration of 9 February, 2005 (IBC, 2005).

Article 18, which appears in the Declaration as the first article in the section entitled 'Application of the Principles', corresponds to five articles appearing in the Fourth Outline in the section entitled 'Implementation Principles', and five articles appearing in the preliminary draft in the section entitled 'Conditions for Implementation'.

The following table describes the last three stages of evolution of Article 18. In this table, the script of Article 18 is spaced out to illustrate correspondence (or lack of correspondence) between the text of Article 18 and the texts of the five precursor articles of each of the other two versions.

Fourth Outline	Preliminary Draft	Declaration
Implementation Principles	Conditions for Implementation	Application of the Principles
Article 18 – Honesty and Integrity Any decision or practice shall: i) be made or carried out with professional independence and intellectual honesty; respect the need for integrity in scientific and other research; avoid conflict of interest; and ii) pay due regard to the need to share knowledge about such decisions and practices with the persons affected, the scientific community, relevant bodies and civil society.	**Article 17 – Honesty and Integrity** Any decision or practice should be made or carried out with: i) professionalism, honesty and integrity; ii) declaration of all conflicts of interest, and iii) due regard to the need to share knowledge about such decisions and practices with the persons affected, the scientific community, relevant bodies and civil society.	**Article 18 – Decision-making and Addressing Bioethical Issues** (1) Professionalism, honesty, integrity and <u>transparency</u> in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge.

Fourth Outline	Preliminary Draft	Declaration
Article 19 – Transparency and Openness Any decision or practice shall: i) be made transparently and openly; ii) be available for appropriate scrutiny by the persons concerned and by civil society; and iii) be susceptible to informed, wide and pluralistic public debate; iv) be subject in respect of all forgoing paragraphs to respect for privacy and confidentiality, as stated in Article (13).	**Article 18 – Transparency** Any decision or practice should, subject to the provisions on privacy and confidentiality in Article (11): i) be made or carried out transparently and openly; ii) be available for appropriate scrutiny by the persons concerned and by civil society; and iii) be susceptible to informed, wide and pluralistic public debate. * Corresponding text appears in opening statement of this article (underlined above): subject to the provisions on privacy and confidentiality in Article (11).	* 'Transparency' appears underlined in the first sentence of sub-paragraph (1) above. * Corresponding text appears in sub-paragraph (3) below.
Article 20 – Fair Decision-making Any decision or practice, where differences arise, shall be resolved following full and free discussion and in accordance with fair procedures and shall be determined with particular regard to the circumstances of to the persons concerned;	**Article 16 – Decision-making** Any decision or practice should: i) be made or carried out following full and free discussion and in accordance with fair procedures;	
Article 21 – Scientific and Rational Requirements Any decision or practice shall: i) be made on the best available scientific evidence; ii) pay due regard to any different information on the subject reasonably available to the decision-maker; iii) be considered rigorously and based on the principles set out in this Declaration; iv) observe, when appropriate, proper procedures of risk assessment; and v) be considered individually; allowing for the possibility of exceptions to general rules and practices.	ii) be made or carried out on the best available scientific evidence and methodology; iii) pay due regard to any different information on the subject reasonably available to the decision-maker; iv) be considered rigorously and based on the principles set out in this Declaration; v) observe, when appropriate, proper procedures of risk assessment, management and prevention; and vi) be considered individually, having regard to the circumstances of the persons, groups and communities concerned.	Every endeavour should be made to use the best available scientific knowledge and methodology in addressing…

Fourth Outline	Preliminary Draft	Declaration
Article 22 – Periodic Review Any decision or practice, including those depending upon specialized scientific or other knowledge, shall take into account the need to reconsider regularly the state of such knowledge and different opinions about it and the need to engage in a regular dialogue with: i) persons affected by any such decision or practice; ii) members of relevant disciplines; iii) appropriate bodies; and iv) civil society.	**Article 19 - Periodic Review** Any decision or practice, including those depending upon specialized scientific or other knowledge, should take into account the need to reconsider periodically the state of such knowledge and different opinions about it and the need to engage in a regular dialogue with: i) persons affected by any such decision or practice; ii) members of relevant disciplines; iii) appropriate bodies; and iv) civil society.	and periodically reviewing bioethical issues. (2) Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.
* Text of Article 19 (iii)	*** Text of Article 18 (iii)** **Article 21 – Promoting Public Debate** States should promote opportunities for informed, pluralistic public debate, ensuring the participation of all persons and bodies concerned, including relevant ethics committees and non-governmental organizations, and the expression of various socio-cultural, religious, philosophical and other relevant opinions.	(3) Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

EXPLANATION OF THE ARTICLE

Ethical reflection should be an integral part of the process of scientific and technological developments, and hence bioethics should play a predominant role in the choices and decisions that need to be made concerning issues arising from such developments. Hence, the process of decision-making, and the individuals and institutions involved in this process, should be characterized by professionalism, honesty, integrity and transparency.

Article 18 identifies six main areas of application of the four characteristics (professionalism, honesty, integrity and transparency):

a. declaration of all conflicts of interest;
b. appropriate sharing of knowledge;
c. using the best available scientific knowledge and methodology;
d. periodic reviews;
e. dialogue on a regular basis; and
f. informed pluralistic public debate, seeking the expression of all relevant opinions.

Conflict of interest refers to a clash between the public interest or professional and legal duty and the private interest of the individual concerned. It commonly arises in a context where public officials and fiduciaries have a special relationship to, or interest in, a specific matter. Conflict may occur between public, academic and business interests, or between medical, scientific and economic interests.

Article 18 prescribes the need to reconsider regularly the state of specialized scientific or other knowledge and the need to engage in a regular dialogue with the wider society. Periodic review is a profound, systematic dialogue with society. Its aim goes beyond providing up-to-date information, as it also promotes continuous ethical social reflections on scientific knowledge.

Professionalism leads to a process based on proper education, training, expertise and skills. Professionalism also implies declarations of all conflicts of interest, use of best available scientific knowledge, having regard to the circumstances of the persons, groups and communities concerned, periodic review, regular dialogue and informed pluralistic public debate.

Honesty leads to declarations of conflicts of interest, using the best available scientific knowledge and methodology, and appropriate sharing of knowledge with the persons affected, the scientific community, relevant bodies and the civil society.

Respecting the need for *integrity* in scientific or other research leads to declarations of all conflicts of interest, appropriate sharing of knowledge, use of best available scientific knowledge, and periodic reviews.

Transparency leads to decisions and practices which are made transparently and openly, availability of outcomes for appropriate scrutiny by the persons concerned and by civil society, and to a continuous process of dialogue on a regular basis, periodic reviews and informed pluralistic public debate, seeking the expression of all relevant opinions.

Transparency is a very important condition for principled decision-making and sound practice within bioethics. Interpretation of scientific discoveries has many pitfalls. Ethical analyses are not necessarily based on an accurate assessment of scientific developments, and these interpretations sometimes misread the effects of applying new biotechnologies. Moreover, interpretations may also be distorted due to factors that are entirely independent of scientific research. The complex issues in the contemporary life sciences and biotechnology have to be addressed within a broader cultural and social context. Trust in science can be enhanced by making the procedures and methodologies of science and technology more transparent and accessible to the public.

RELATIONSHIP OF THE ARTICLE TO THE DECLARATION AS A WHOLE AND TO OTHER DECLARATIONS

As stated earlier, since Article 18 provides basic ethical values to be observed in each decision or practice targeted by the Declaration, then it may be considered relevant to each of the articles expressing the Declaration's principles.

In particular, there exists direct relevance, or even intersection, between Article 18 and two of the previous articles. First, we must recall that Article 18 in the Declaration, unlike the previous versions, does not subject transparency to the provisions of privacy and confidentiality. Nevertheless, transparency in Article 18 is directly relevant to Article 9 (Privacy and Confidentiality) as some decisions in the field of bioethics have a confidential nature. For example, in decisions on the medical treatment of an individual, personal information provided by the patient should necessarily be taken into account. Sometimes legally protected commercial confidentiality may impose restrictions on publicity to outsiders. The information provided should be regarded as a private and confidential matter. The structure of the Declaration makes this distinction evident by enlisting *privacy* and *confidentiality* among principles, while including *transparency* at the level of application of the principles. By adopting appropriate expedient implementation that involves consideration of privacy and confidentiality, one can usually avoid the risks of disclosure whilst achieving a desirable level of transparency and public participation and knowledge.

Secondly, Article 18 in the Declaration, unlike the previous texts, does not include the choice of individually tailored decision-making that takes into consideration the circumstance of the persons affected or concerned. If a different choice (which does not take into consideration the circumstances of the persons affected) is concluded as a result of pluralistic public debate, then due regard should be paid to stipulation of Article 3.2: 'The interests and welfare of the individual should have priority over the sole interest of science or society.'

Article 18 expresses ethical values in line with four articles of the Universal Declaration on the Human Genome and Human Rights (1997):

a. Article 13

   'The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity,…'

b. Article 18
'States should make every effort … to continue fostering the international dissemination of scientific knowledge…'
c. Article 19
'… States should seek to encourage measures enabling … the free exchange of scientific knowledge in the areas of biology, genetics and medicine to be promoted.'
d. Article 21
'States … should also undertake to facilitate on this subject an open international discussion, ensuring the free expression of various socio-cultural, religious and philosophical opinions.'

Article 18 also expresses ethical values in line with six articles of the International Declaration on Human Genetic Data (2003):

a. Article 6: Procedures
'... on the basis of transparent and ethically accepted procedures.'
b. Article 15: Accuracy, reliability, quality and security
'They should exercise rigour, caution, honesty, and integrity...'
c. Article 18: Circulation and international co-operation
'(b)… to continue fostering the international dissemination of scientific knowledge…'
'(c)… in order to foster the sharing of scientific knowledge…'
d. Article 20: Monitoring and management framework
'… based on the principles of independence, multidisciplinarity, pluralism and transparency…'
e. Article 23: Implementation
'… to participate in generating and sharing scientific knowledge…'
f. Article 24: Ethics education, training and information
'… aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large.'

APPLICATION OF THE ARTICLE

In commenting on the application of Article 18, it should be first stated that Article 18 is the first, and perhaps the most important, article appearing in the section entitled: 'Application of the Principles'. The article delineates basic ethical values that should be promoted in every decision or practice related to medicine, life sciences and related technologies. The article addresses a wide range of stakeholders including persons affected by any such decision or practice, members of relevant disciplines, appropriate bodies and civil society.

In the field of bioethics, standard-setting and political decision-making require informed pluralistic debate with the widest possible involvement of the public, ensuring the participation of all persons and bodies concerned, including relevant ethics committees and non-governmental organizations, and the expression of various socio-cultural religious, philosophical, and other relevant opinions.

The obligation is imposed on Member States, not just on ethics and bioethics committees. In public debate, ethical issues are addressed in a wider arena that offers the public a possibility to be involved actively. Public debate is often a formality, as most of the time no prescribed procedure exists to ensure that the public is informed. In complex issues, such as genetic research, the public should have access to proper and necessary information in order to participate effectively in such a debate.

Hence, it is essential that bioethics education and training at all levels be provided for all persons and bodies concerned, stressing in particular the ethical values embodied in Article 18. Also necessary are modes and mechanisms for bioethics education, training and dissemination of information and knowledge relevant to the application of Article 18. It is expected that such modes and mechanisms will be presented in the commentary on promotion of the Declaration.

The use of 'should,' rather than 'shall', in Article 18 is justified by the need for more flexibility in the application of principles than in the expression of principles. In contrast with the principles that provide guidance for the content of decision-making, the applications of the principles are not thematic and do not deal with the content of ethics decisions, but rather refer to the process leading to ethically acceptable decisions in various fields of bioethics.

It is worth noting several other modifications on earlier versions which resulted in flexibility in the application of Article 18: 'Avoid conflict of interest' was modified to 'declarations of all conflicts of interest'; 'due regard to the need to share knowledge' was modified to 'appropriate sharing on knowledge'; and 'be made on the best available scientific evidence' became 'every endeavour should be made to use the best available scientific knowledge and methodology'.

Finally, it is understood that the Declaration represents the text of common agreement among all Member States, and hence lead to adoption and acclamation by the General Conference of UNESCO. Then, it is left to each State, on the basis of regular dialogue and informed pluralistic public debate, to express in its domestic law the desired degree of flexibility (or rigidity) in implementing the stipulations of Article 18 of the Declaration.

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Chapter 21

ARTICLE 19: **ETHICS COMMITTEES**

Claude Huriet

Article 19 – Ethics committees

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

a. *assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;*
b. *provide advice on ethical problems in clinical settings;*
c. *assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;*
d. *foster debate, education and public awareness of, and engagement in, bioethics.*

BACKGROUND

At the beginning of the Universal Declaration on Bioethics and Human Rights, the necessity to reflect on the ethical consequences of 'the rapid developments in science and technology, which increasingly affect our understanding of life and life itself' was felt. Moreover, the conditions on the way to proceed to reflect on the issues have to be clearly defined so that they respect human rights and human dignity.

The Declaration is addressed to Member States (Article 1) and '…it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private'. In order to 'reflect on ethical issues' and 'to provide guidance and practices', the Declaration recommends the setting up of bioethics committees (Article 19).

Article 19 consists of at most 10 lines. However, it holds an important position in the structure and application of the Declaration.

WHY IS THIS ARTICLE IN THE DECLARATION?

The ethical approach is in fact a continuous questioning, involving necessary and difficult research and answers to 'dilemmas and controversies that science and technology present for humankind and for the environment' (paragraph four of the Preamble). Research in the field of bioethics is vital as it concerns the life and dignity of human being. 'Mankind is given the opportunity to question the moral importance of his intervention in life' (Potter, 1970; 1971).

This questioning relies on 'a pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole' (Article 2(e)). This dialogue cannot be established and developed unless structures fostering diversity of competences and favouring the expression of a variety of ideas, as well as values susceptible to clarifying orientations and choices, are present in the field of biomedicine, that is medicine using life sciences for living beings.

Article 19 of the Declaration relies on the existence and experiences of ethics committees that were constituted some 30 years ago in many countries. The most ancient ones were created in response to questions triggered by human experimentation, and the reflections were published in international journals. Bioethics committees intervene as guarantors for the respect of ethical conditions during human experimentation, and their field of reflection has been extended little by little.

HOW HAS THE ARTICLE DEVELOPED?

Already in the first meeting of the Drafting Group of the International Bioethics Committee in April 2004 reference was made to the need to promote and establish national bioethics committees and review boards (IBC Drafting Group, 2004). The same brief text ('the promotion and establishment of national bioethics committees and review boards at appropriate levels') was reiterated in the Second Outline of a Text, under the heading 'Procedures [Procedural Principles]' (IBC, 2004a). An elaborated text in a separate article appeared for the first time in the Third Outline, published in August 2004 (IBC, 2004b). The section on procedures presented the following article on ethics committees:

> Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order:
>
> (i) to assess the ethical, legal and social issues related to scientific research projects and technological developments; and

(ii) to devise guidelines and recommendations on issues within the scope of this Declaration, in accordance with the principles set out therein.

The text of the draft article remained virtually unchanged in the Fourth Outline of December 2004 (IBC, 2004c). Only the title and first sentence were changed by mentioning 'ethics and bioethics committees'.

The Preliminary Draft Declaration, issued by the IBC in February 2005, presents the text in an expanded and revised formulation:

> Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:
>
> (i) assess the ethical, legal and social issues related to scientific research projects involving human beings;
> (ii) formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration, in accordance with the principles set out herein; and
> (iii) foster debate and education in bioethics (IBC, 2005).

This formulation gave rise to considerable debate during the Second Session of the Intergovernmental Meeting of Experts in June 2005. In general, it was observed that the draft text covered the concerns expressed by States. Certain delegates insisted that this article should apply to all types of ethics committees; not only institutional committees, but also research committees and clinical ethics committees. Other delegates wished to include an explicit reference to the role of advisory committees in the clinical context as well as in relation to scientific and technological developments. Emphasis was also placed on the awareness and engagement of the public in the field of bioethics, which ethics committees should strive to promote. These concerns led to several amendments of the text. The governmental experts agreed on the reformulation of the text of the article (Report expert meeting, 2005). This formulation was adopted by the General Conference several months later.

WHAT IS THE SIGNIFICANCE OF THE ARTICLE?

Addressing bioethical questions (Article 18), evaluation and management of risk (Article 20) and transnational practices (Article 21) have been evoked in the text of the Declaration in the application of principles section.

The three articles implicitly refer to Article 19 'Ethical committees', whose attributes are the evaluation of ethical problems linked to scientific and

technological progress, formulation of advice on ethical dilemmas, educating and mobilizing the public.

Let us consider the four attributes of bioethics committees that make them irreplaceable for the application of the principles of the Declaration.

a. The evaluation of ethical, legal, scientific and social problems relevant in human research. Development of research has to contribute to human knowledge, the improvement of health and living conditions. But the finalities of research alone cannot justify practices that affect human dignity or favour the interest of society. The evaluation of diverse problems (ethical, legal, scientific and social) (transversal approach) implies that the composition of committees should reflect the exigencies and multidisciplinary nature of such ethical questions.
b. Issuing advice 'on ethical problems in clinical situations' transcribes the mode of expression during reflections in committees. The diversity of clinical situations, for example the complexity of the evaluation mentioned above, the pluralism and multidisciplinary nature of committees, rarely render their decisions imposable on everyone. This is the reason why committees issue advice or recommendations that enlighten public opinion and constitute an aid to decisions. It is only the law that may authorize or forbid practices where the ethical consequences have been evaluated.
c. The evaluation of scientific and technological development constitutes an essential part of reflection of committees that should not however be an 'expert committee'. The evaluation of scientific development always includes a large margin of uncertainty, and in practice the difference between hope fostered by progress and the consequences and effective results is often significant. Ethical committees should also reflect on the conditions of accessibility to scientific progress. In defining the objectives of the Declaration, Article 2(f) mentions 'equitable access to medical, scientific and technological developments...', while Article 15 is wholly dedicated to 'sharing of benefits'.
d. Informing and mobilizing the general public on bioethics matters is important. Whether interested in scientific development or hopeful about health issues, the general public may be biased by messages amplified by the media towards expected benefits from development while minimizing or silencing the limits, inconveniences or risks.

Sensitization and the engagement of the general public favour citizen awareness about the problems, thereby helping them in exercising 'their autonomy and individual responsibility' (Article 5). Sensitization of citizens often is the first step in raising awareness of authorities because it is up to the States (Article 22) 'to take appropriate measures to give effect to the principles set out in this Declaration in accordance with international human rights law'. Legislative measures are part of the appropriate measures. It should be noted that, generally, 'ethical reflection precedes law'.

HOW CAN THE ARTICLE BE APPLIED?

'States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees' (Article 22.2). Therefore, if States should 'encourage' the establishment of committees, there would be no opposition for committees to proceed on personal initiative provided they satisfy the requirements of pluralism, multidisciplinarity and independence. The main question therefore concerns the legitimacy of the committees. In fact, the recommendations that the committees might formulate can be considered only if the body is competent, independent and transparent. Who will decide if it is not the State? But then, what about the independence of the committees?

This question, although fundamental, remains unresolved. Ethics committees can demonstrate their authority only by respecting pluralistic principles, for example by representing different schools of thought and by accommodating personalities with recognized competencies and moral authorities. By organizing public debates, ethics committees can demonstrate that these guarantees are respected thereby reinforcing the authority of these bodies.

International ethics committees meetings under the aegis of UNESCO would favour exchanges between committees. Moreover, the meetings would enrich the reflection of committees and ensure that the cultural diversity is compatible with the founding principles of the Universal Declaration on Bioethics and Human Rights.

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Chapter 22

ARTICLE 20: **RISK ASSESSMENT AND MANAGEMENT**

Michèle S. Jean

Article 20 – Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

WHY IS THIS ARTICLE IN THE TEXT?

Louis D. Rubin rightly wrote in 1991:

> The Twentieth Century started with a euphoria of new wealth, relative peace, and industrialization, only to descend into a chaos of regional and worldwide wars. These and other catastrophes crushed illusions about the perfectibility of society and our species, leaving us less idealistic and more appreciative of the continuing uncertainty of our future.
>
> Ideas drove change in this past century. Stephen Lagerfeld summed it up cogently in his 'Editor's Comment' in the Autumn 1999 issue of Wilson Quarterly: 'Apart from the almost accidental tragedy of World War I, the great clashings of our bloody century have not been provoked by the hunger for land, or riches, or other traditional sources of national desire, but by ideas — about the value of individual dignity and freedom, about the proper organization of society, and ultimately about the possibility of human perfection.' Risk management is one of those ideas, the sense that a logical, consistent and disciplined approach to the future's uncertainties will allow us to live with them prudently and productively, avoiding unnecessary waste of resources. It goes beyond faith and luck, the twin pillars of managing the future before we began learning how to measure probability (*Risk Management Report*, 1999; Rubin, 1991).

In the last decades, scientific certitude has been shaken by many environmental and health disasters like the contamination of blood, Seveso, Bhopal, Chernobyl, the Tsunami, and the New Orleans disaster. These events have shown the weaknesses of our risk management strategies and have opened discussions on the inclusion of the precautionary principle as a tool in the decision-making process:

> Few policies for risk management have created as much controversy as the precautionary principle. Emerging in European environmental policies in the late 1970s, the principle has become enshrined in numerous international treaties and declarations. It is, by the Treaty on European Union (1992) the basis for European environmental law, and plays an increasing role in developing environmental health policies as well (Foster, Vecchia and Repacholi, 2000).

As we know, one of the problems of the precautionary principle is that: '… as a policy tool, is its extreme variability in interpretation. One legal analysis identified 14 different formulations of the principle in treaties and nontreaty declarations.' (Foster *et al.*, 2000). On the other hand: 'Perhaps the main originality of this new tool of risk management is that measures need to be taken before definitive scientific evidence of the harmful effects becomes available' (Andorno, 2004).

Responsibility is an important principle in ethics. It underlies many of the well-known ethical principles stated in the Universal Declaration on Bioethics and Human Rights like autonomy, consent, social responsibility, and solidarity. It also underlies the articles related to respect for the biosphere or respect for future generations. In 1999, the Budapest World Conference on Science, organized by UNESCO, stated that: 'Governments should encourage the setting up of adequate mechanisms to address ethical issues concerning the use of scientific knowledge and its applications, and such mechanisms should be established where they do not yet exist' (UNESCO, 1999). In the *Report of IBC on the Possibility of Elaborating a Universal Instrument on Bioethics*, paragraph 13 reads: 'States have a special responsibility not only with respect to bioethical reflection but also in the drafting of any legislation that may stem therefrom. It is true that, in matters of bioethics, many States have framed laws and regulations aimed at protecting human dignity and human rights and freedoms' (IBC, 2003).

We can say that responsibility has been a preoccupation of UNESCO in fulfilling its ethical mission, and this objective is reflected in all documents produced either by the IBC or by COMEST. It is also reflected in the other

two declarations related to bioethics (UNESCO, 1997; UNESCO, 2003). We can argue that the IBC really wanted, from the beginning of its work on this Declaration, to send a clear message to policy-makers and scientists about their obligation to act in a responsible manner and to move to action when necessary.

In the following pages, we would like to track the steps that lead to the final formulation of the article on risk assessment and management because we feel that it shows the process through which the IBC, influenced by the involved stakeholders, arrived at its final formulation of the article. The article was then submitted to government experts who arrived, on a difficult issue, at a pragmatic compromise. To achieve this goal, we will use a process-oriented methodology to review the different formulations of the article.

At its first meeting, the IBC Drafting Group already discussed:

> … the need to foresee provisions concerning the procedure to be followed at national and international level in the framework of science and technology, particularly with regard to recourse to democratic and transparent procedures - for example the creation of national bioethics committees and review boards should be called for and encouraged, as well as a system of responsibility at national and regional level and, on an international level, reflection on procedures regulating trans-border flows (IBC Drafting Group, 2004a).

It came back to this idea at its fourth meeting. In paragraph 16, the minutes of the fourth meeting read:

> At the suggestion of a member of IBC, the Drafting Group examined the possibility of including in the Declaration the principle of precaution applied to the field of bioethics – being aware that this principle was not the object of unanimous agreement in the international community. Nevertheless some members felt that the application of this principle in certain fields could appear to be unsuitable – for example in matters of scientific research. Others felt that caution was necessary as this principle could sometimes be used for purposes contrary to human rights and fundamental freedoms. The Group thus decided not to include a specific article concerning the principle of precaution but that it be reflected in the procedural part by including a provision on risk assessment (IBC Drafting Group, 2004b).

The discussions showed mixed views about the precautionary principle and a certain fear that it would not be accepted as such by many governments.

So, a pragmatic compromise was to have an article on risk in the section dedicated to procedures. After that discussion, the Drafting Group came back later to this topic and the minutes of the same meeting report the following in paragraph 23:

> With regard to risk assessment, the Group decided to accompany the article with a provision in the section devoted to the implementation which defines the responsibility of States to establish and guarantee a framework of management and assessment of risks. This framework should foresee the identification of the issues involved, the characterization of the risks and benefits, the development of options, the implementation of the decision and the monitoring of the results. (IBC Drafting Group, 2004b)

To reflect this position, the Third Outline of the Declaration included the following:

> **Article 19 – Risk assessment**
> When there is scientific evidence of threats of serious or irreversible damage to public health and human welfare or the environment [biosphere], provisional adequate and proportionate measures shall be taken in a timely manner. Such measures shall be based on the best scientific knowledge available and carried out in accordance with the principles set out in this Declaration and with respect to human rights and fundamental freedoms (IBC, 2004a).

At its sixth meeting, in December 2004, the Drafting Group discussed the results of the written consultation that had taken place from October to December 2004. The reactions and comments of Member States on Article 23 were going in all directions, already showing how difficult it would be to obtain a consensus. Some countries wanted to strengthen the principle and clearly mentioned the precautionary principle; others suggested rewording it without mentioning the precautionary principle, but adding words that would clarify situations when there is uncertainty; and finally others wanted to delete the article completely.

The Fourth Outline of the Declaration on Universal Norms on Bioethics was finalized by the Drafting Group of the International Bioethics Committee at its sixth meeting, held in Paris from 12 to 14 December 2004. Taking into account those comments, as well as comments formulated at the Fourth Meeting of the UN Inter-Agency Committee on Bioethics (2004) the Fourth Outline of the Declaration was finalized and Article 23 read as follows:

> **Risk assessment**
> When scientific evidence of serious or irreversible damage to public health or human welfare or the environment is not sufficient, provisional, adequate and proportionate measures shall be taken in a timely manner. Such measures shall be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect to human rights and fundamental freedoms (IBC, 2004b).

Finally, in January 2005, the IBC finalized the Preliminary Draft Declaration on Universal Norms on Bioethics following a session of the IGBC, a joint session of IBC and IGBC in January 2005 and an Extraordinary Session on 28 January 2005. During the joint session with the IGBC, the following comment was made by governments:

> With regard to the article dealing with risk assessment, the participants wished that the formulation of the text be revised for purposes of clarity. It seemed to them that, in its present draft, the text amalgamated cases where risks were known and scientifically established and cases where a threat of serious or irreversible prejudice existed even though there may not yet be any scientific certainty (Joint Session, 2005).

These comments lead to the reformulation of the article that was then drafted to make a clear distinction between evidence and threat of risk. Concurringly, the preliminary draft of the Declaration included in the section on Conditions for implementation the following article:

> **Article 22 – Risk assessment, management and prevention**
> a) When evidence of serious or irreversible damage to public health or human welfare becomes available, appropriate measures should be taken in a timely manner.
> b) When there are threats of serious or irreversible damage to public health or human welfare, and there is not yet scientific certainty about such threats, provisional, adequate and proportionate measures should be taken in a timely manner. Such measures should be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect for human dignity, human rights and fundamental freedoms (IBC, 2005).

This preliminary draft concluded the work of the IBC. The draft had then to be examined and discussed by governmental experts.

At their first meeting in April 2005, governmental experts were provided with an Explanatory Memorandum. On the article about risk, this memorandum gave the following explanation:

> **Article 22 – Risk assessment, management and prevention**
> Article 22 deals with two different scenarios. Paragraph a) deals with those cases in which there is evidence of serious or irreversible damage to public health or human welfare. Paragraph b) concerns situations in which there are threats of serious or irreversible damage to public health or human welfare. Paragraph b) describes the procedures to be followed in cases where there are new scientific and technological developments that may lead to serious or irreversible damage to public health and human welfare or to the environment, although the probability of such harm occurring is not known with scientific certainty.
> In such situations of uncertainty, timely measures shall be taken to assess the risks involved. The assessment procedures should evaluate the ethical issues at stake. The outcome of the assessment may vary from accepting the development, regulating and monitoring the development, accepting a moratorium, or prohibiting the development.
> The measures taken under Article 22 shall be based on the best scientific knowledge available and carried out in accordance with the principles set out in the Declaration and with respect to human rights and fundamental freedoms (UNESCO, 2005).

At that same meeting, the Chair of the IBC, in her presentation of the draft, provided the following explanation about the article: 'In particular, Article 22, concerning risk assessment, management and prevention, has certainly evolved and henceforth distinguishes between two types of scenario: those where the risks are known and scientifically established, and those where there is a threat of serious or irreversible damage, without this, however, being known with scientific certainty.' (Jean, 2005)

The article was further discussed in the 2nd Session of Governmental Experts in June 2005. Concerning Article 22, the minutes report that:

> … while some delegates felt that this provision does not come within the field of application of the Declaration, others felt, on the contrary, that it was important to provide an ethical framework to assess and manage risks in the field of medicine, life sciences and associated technologies. Finally, the meeting decided to retain the article by

> amending it in such a way as to formulate a general principle without going into detail (as reflected in the final Declaration) (Report expert meeting, 2005).

This quote from the minutes shows the division between delegates, division in line with comments received in the second written consultation. The conflicting views about the opportunity to include such an article are, in a sense, a good illustration of the international discussion about risk management strategies and the precautionary principle.

The section under which the article appears is labelled 'Application of the principles' and regroups the action-oriented articles. The article on risk assessment and management, as approved by the General Conference, reads: 'Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.'

WHAT DOES THE TEXT MEAN?

Although much more timid than the IBC would have liked it to be, the mention of risk assessment and management appears for the first time as a stand alone article in a UNESCO declaration related to bioethics. The Universal Declaration on the Human Genome and Human Rights in Article 19 referring to international co-operation with developing countries promotes: 'assessment of the risks and benefits pertaining to research on the human genome to be carried out and abuse to be prevented.'

There is at least recognition of the fact that there are risks attached to the development of medicine, life sciences and technologies. Considering all the difficulties that are still facing the definition of risk and of terms such as 'appropriate', 'plausibility', 'probability', and the fact that the discussions about the Declaration were held against a background of many cultural contexts, we can say that this article should be seen as a step in the right direction. On the negative side, the fact that the article concludes by 'should be promoted', instead of 'shall be promoted' weakens the engagement of Member States to follow up.

We know that many countries, especially European countries, have laws, policies or regulations to manage risks and to deal with the precautionary principle, which is not the case for many developing countries. The meaning of the text has to be explained in the context of the full Declaration. For example, Article 2 (d), (g), and (h) command respect for research but also for future generations and biodiversity; Article 5 on autonomy and individual responsibility; Article 14 on social responsibility and health; Article 16 on protecting future generations; Article 17 on protection of the environment, the

biosphere and biodiversity; and Article 22 on the role of States are all pointing in the direction of risk management and precaution, and can all be invoked in relation to Article 20. The international texts, listed in the Preamble, are also references that contribute to the overall interpretation of the Declaration.

Seen in that perspective, the article is by essence a call, at the same time, to reflection and action from the scientific community and Member States:

> When ethics is integrated into political and legal thinking, one should be careful to, on the one hand, acknowledge the diversity and plurality of ethical thinking and, on the other hand, strive for as much practical consensus on moral judgements as is possible (COMEST, 2005).

HOW CAN THE TEXT BE APPLIED ?

Discussing the influence of declarations, the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) affirms:

> Declarations of principles, though not binding, can influence the elaboration, interpretation and application of the international laws of Member States of the international organizations that conceived or endorsed the declarations. The reason is that, in joining an international organization, a State accepts a number of obligations (op.cit., p. 17).

On the same topic Noëlle Lenoir and Bertrand Mathieu wrote:

> Thus bioethics seems to constitute a privileged territory for a particularly modern type of law-making that favours maturation and promotes negotiation, avoiding the direct imposition of imperative norms (Lenoir and Mathieu, 2004: 50).

The application of the article has also to be construed within the framework of the overall Declaration. The developments of science and technologies have already shown the importance of assessing and managing risks. The IBC wanted policy-makers to feel responsible for these developments, and the scope is clear about that when it says in Article 1:

> 1. This Declaration 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.

2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

The IBC had long discussions about including or not including specific issues in the Declaration, but as suggested during the consultation, it was decided to use the Declaration as a general framework to guide States in the development of their legislations, policies and regulations.

The specific issues that were mentioned in the written consultations are the following:

- *beginning of life:* abortion, prenatal diagnosis, pre-implantation genetic diagnosis, reproductive technologies, sex selection;
- *end of life:* concepts of death, prolongation of life, euthanasia, palliative care;
- *genetics and molecular biology:* genetic counselling, genetic screening and testing, gene therapy, gene patenting, genetic enhancement, GMOs, population genetics, cloning (reproductive cloning and non-reproductive cloning);
- *intellectual property rights;*
- *health care systems:* access to drugs, access to health care, allocation of health care resources, quality of care, right to health care, rights of vulnerable persons;
- *human genetic data and other personal health care data;*
- *organ and tissue transplantation;*
- *public health:* HIV infection and AIDS, other infectious diseases (malaria, tuberculosis…), policies regarding vulnerable populations;
- *research:* research with human subjects, embryo research, behavioural research, international and transnational research.

In the coming years, all these issues will all raise questions related to risk assessment and risk management, as well as to the precautionary principle. This is why this article is so important and prompts us to continue to seek its clarification and field of application.

CONCLUSION

The United Kingdom Interdepartmental Liaison Group on Risk Assessment wrote in *The Precautionary Principle: Policy and Application:* 'Although it is widely accepted that the precautionary principle should be invoked in deciding

how hazardous activities should be addressed, there is considerable debate about what the principle means, and about how it should be applied in practice' (ILGRA, 2002). The debate on the way to include an article about risk management in the Declaration, the fears it raised about stating something that could be confused with an application of the precautionary principle, and the divergent views expressed on the issue show how difficult it still is to have a conversation on that matter and how important it is to pursue the debate.

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Chapter 23

ARTICLE 21: **TRANSNATIONAL PRACTICES**

Leonardo D. de Castro

Article 21 – Transnational practices

1. *States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.*
2. *When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.*
3. *Transnational health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognised.*
4. *When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation.*
5. *States should take appropriate measures, both at the national and international levels, to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials.*

WHY IS THIS ARTICLE IN THE TEXT OF THE DECLARATION?

When the IBC looked into the feasibility of formulating a universal declaration on bioethics, it took note of the transnational character of a number of practices that tended to raise bioethical controversies. As some practices cut across national boundaries, they give rise to ambiguity regarding the laws or regulations that should be applicable, or the authorities that have the right and

legitimate power to exercise sovereignty; therefore the need to call attention to these transnational practices and the ethical issues that they generate was one of the main reasons why the IBC considered it important to endorse the drafting of a universal instrument on bioethics.

The IBC noted in its *Report on the Possibility of Elaborating a Universal Instrument on Bioethics* (2003):

> A growing number of scientific practices have extended beyond national borders. The import and export of embryos and embryonic stem cells, organs, tissues and cells have called attention to disparities between policies promulgated in the countries involved. The transborder flow of tissue collections, DNA samples and genetic data has also raised questions about the need for harmony among the pertinent regulations in different countries (IBC, 2003).

Regarding the conduct of biomedical research and experiments involving several countries, the Report of the IBC noted that these have highlighted the need for consistency in regulations and policies in both the developing and the developed world:

> These practices and experiences point to the need for people of all nationalities and their governments to look beyond their borders in understanding the bioethical issues that are being generated and providing solutions that are fair to all and compatible with the plurality of values and interests of the international community (IBC, 2003).

Thus, according to the report, the increasing globalization of biomedical research has given rise to more ethical issues in the involvement of human subjects, while enabling sponsor countries to conduct research in poor communities with greater convenience, co-ordination and efficiency. In such a context, there is a need for greater vigilance to guard against evolving forms of exploitation. Although international collaborative research is a necessary feature of co-operative initiatives to address global health concerns, there is an imperative for universal ethical standards that promote equitable treatment for the rich and the poor alike.

THE EVOLUTION OF THE ARTICLE

The inclusion of an article on transnational practices was a direct response to suggestions during the initial process of consultations that the Declaration encourage the setting up of bodies that could issue regulations concerning

transnational practices. In particular, commentators observed that in the context of North-South relations, there was good reason to cover transnational research. The article referred exclusively to research involving different countries in its first formulation. However, subsequent deliberations within the IBC and the IGBC, as well as consultations with various stakeholders, clearly indicated a need to expand coverage. A revised version of the Draft included a broader provision, calling on States to take appropriate measures to ensure that any activity with bioethical implications undertaken by different states complies with the principles of the Declaration.

Further deliberations and consultations affirmed the importance of the provision and noted the need to avoid multiple ethical standards arising from the involvement of multiple countries in a research project. There was also a recommendation to emphasize that health research conducted in a particular country should be responsive to the needs of the citizens of that country, and in general, that research should contribute to the alleviation of urgent global health problems. The article was further revised to accommodate these points, and specific reference was made not only to the multi-country ethical review of health research, but also to other transnational practices involving bioterrorism and illicit traffic in organs, biological tissues and samples, genetic resources and genetic-related materials.

Several factors have helped to bring about a situation that makes it important and timely to work for the harmonization of discordant national policies toward transnational practices. The first factor is the ease of international travel. Individuals are able to move across national boundaries more quickly because of faster and more efficient means of transport. In addition, States have generally been more liberal in their attitude to cross-border travel and migration.

The second factor is a result of the first, and it consists in greater interaction among people from different countries, as well as greater interdependence among people of various nationalities concerning their needs. Greater interaction means, for example, that researchers from one country can recruit human subjects from other countries, patients (provided they can so afford) can seek the services of doctors and of other health care professionals almost anywhere in the world, wealthy nations can recruit health care workers from a global health care labour market, and communicable diseases can spread more quickly and widely, infecting more people from more places.

The third factor is an ethical principle that is enunciated also in the above-mentioned report:

> Any denial of human dignity is an unacceptable denial of the rights of the human person and, as such, concerns the entire international community (IBC, 2003).

Violations of human rights committed anywhere in the world must be the concern of all, even when they are not directly affected by such violations. This basic principle lies at the core of ethical human interaction. It also explains the importance of Article 21 of the Universal Declaration on Bioethics and Human Rights, as it specifically deals with transnational practices relating to bioethics.

These three factors may be seen to relate to all sorts of practices mentioned explicitly in Article 21 of the Declaration – international health research, bioterrorism, and illicit traffic in organs, tissues, samples, genetic resources, and genetics-related materials. They are equally pertinent to other practices that are not explicitly mentioned in the Article but are no less important than those mentioned, and possibly even more significant in terms of overall impact on people's lives – migration of health professionals and the selling and pricing of drugs and medical implements.

WHAT DOES THE ARTICLE MEAN?

The first paragraph makes it clear that the transnational character of some activities should not have the effect of putting them beyond the scope of the principles set out in the Universal Declaration on Bioethics and Human Rights. This implies that activities covered by the Declaration should not be out of the reach of authorities, even if such activities are undertaken in a way that straddles different States, or if there are ambiguities concerning the right or power that some States have to impose rules or regulations pertaining to individuals as they move across national boundaries. The geographical context within which practices take place should not detract from the need to observe the principles set out in the Declaration.

The primary reference of Article 21 is to international health research. The reference has grown in relevance because of controversies arising from fears that research subjects, especially in developing countries and resource-poor communities, are being exploited in the conduct of externally-funded research. Many are rendered vulnerable to exploitation by their poverty and ignorance. The situation could be exacerbated by the mistaken impression that research conducted by scientists from more prosperous countries in poorer nations may be exempted from standard ethical considerations, when people from poverty-stricken areas are so heavily burdened by disease that ethical

considerations have to give way to medical expediency. The exploitation of vulnerable research subjects has been well documented in many situations, and Article 21 confirms the importance of dealing with the problem on a global scale.

Another development that has given rise to this concern about exploitation is the increasing involvement of scientists from developing countries in the conduct of international research, due to capacity-building programmes in the area of health research. Unfortunately, the expansion in research capacity has not been matched by an expansion in the review of capacity for ethics. As developing countries' researchers seek to become truly equal partners in international research, there should be a serious effort to enable them to confront the ethical challenges on an equal footing. Article 21 confirms this need and provides the basis for an international initiative.

The attention paid to transnational research practice is made more relevant also by the growing role of industry in the conduct of clinical trials. The economic forces driving the involvement of transnational companies in clinical trials on biotechnology, pharmaceuticals and medical devices have facilitated the continuing expansion of the global market. However, the expansion has not necessarily resulted in equitable solutions to health problems affecting people in varying economic situations. The market has catered mostly to the needs of the few who are rich, leaving the research and health care needs of the poor severely underserved. Thus, questions concerning the prioritization of health research have persisted, making even more significant the call put forward in paragraph 3 that 'transnational health research should be responsive to the needs of host countries, and that the importance of research contributing to the alleviation of urgent global health problems should be recognized.'

Since international research obviously transcends national boundaries, it must be guided by a clear understanding of the legal and ethical frameworks that are needed to govern the practice. One mechanism that is available for providing clear guidance is the ethics review of research proposals, and Article 21 confirms the need to undertake the exercise not only in the State(s) providing the source of funding, but also in State(s) hosting the research. The double (or multiple) review provides an opportunity for the States involved to clarify their ethical framework and to regulate the practice within their territory.

In general, the ethical or legal implications of some activities or practices performed by individuals or groups in a territory outside their own are easily overlooked. Ambiguities arise because of differences in legislation

or ethical outlook between different states. Some differences in domestic legislation could crop up merely because states do not react to developments in medical technology at the same pace or with the same sense of importance and urgency. Given the numerous controversies that have been experienced in many countries relating to such practices as the illicit traffic in organs or the cross-border transfer of genetic materials, authorities ought to realize the value of appropriate measures as called for in paragraph 5 of the Article.

The provisions of Article 21 must be seen in the broad context of the entire Declaration. The Article bears a direct relationship to Articles 14 and 15, which pertain to social responsibility and the sharing of benefits. By virtue of the broader scope that is inherent in transnational practices, they provide a natural venue for the exercise of social responsibility and the sharing of benefits. Article 21 makes the connection all the more significant through its reference to international research, since many of those who are engaged in this practice have been accused of failing to comply with a social responsibility arising from a fiduciary relationship between researchers and research subjects. They have also been accused of not doing enough to ensure that the poor are able to share in the benefits arising from research outcomes. The provisions of Article 10 on equality, justice and equity provide the general ethical basis for the significance of the provisions on transnational practices, while the provisions of Article 19 provide an elaboration of the role of ethics committees.

HOW CAN THE ARTICLE BE APPLIED?

Article 21 sets a high standard for evaluating transnational practices by providing that these should comply with the regulations that are in place in the countries involved. This confirms a norm that is endorsed by some international guidelines for health research as well as by some international research agencies. Thus, the requirement for an ethics review in the country of the funding source as well as in the countries where research is to be implemented also has the potential to serve as a catalyst for the harmonization of guidelines coming from different States. Moreover, it enables regulatory bodies or review committees to attempt to remove possible inconsistencies between their ethical and legal frameworks.

The ethics review of research also provides a venue for ensuring that the other provisions of Article 21 are respected. The review of proposals enables host States and host institutions to negotiate conditions that could ensure the responsiveness of research to the needs of their population and

to other global health problems. For example, they could ask for ways to get local researchers involved in the project, thus improving their own capacity for carrying out health studies. They could also seek to modify the design of the project in order to increase the likelihood that the information derived will contribute to the solution of local health problems.

Multiple ethical reviews also enable those involved to see the possible benefits even before the initiation of specific projects. Paragraph 4 of the Article confirms the importance not only of entering into negotiations regarding the benefits of research, but also of having equal participation by those involved. Hence, the clear message is to avoid practices that could exploit populations that host international research.

As for other transnational practices, some countries have very specific laws or regulations dealing with organ transplantation, while others have only general laws pertaining to the broad aspects of medical practice or to the disposal of human bodies after death. Hence, uncertainties develop in the specific context of organ retrieval and donation, especially when patients seek the medical services of transplant doctors in countries other than their own, or when medical doctors or organ donors travel outside their own country to provide services or assistance.

Similar uncertainties may also develop in the context of IVF. Although the technique has been practiced in some countries since the late 1970s, there are other countries where it has not been offered to patients because of ethical and legal issues. In these countries, the moral status of the embryo has been regarded as not being any different from that of human beings already born. Local doctors could only do the preliminary testing and prepare the patients. IVF itself is carried out in another country where medical practitioners are not restrained by a similarly conservative moral outlook. Thus couples have been able to take advantage of the ethical and legal differences to obtain services that would not have been available to them otherwise.

Similar experiences have been observed in the practices of abortion and embryonic stem cell research as individuals seek opportunities for medical services or for scientific research that they could only avail of outside their national borders. Article 21 does not endorse uniformity in dealing with these differences. However, it signals a need for vigilance, with the reminder that any activity undertaken, funded or otherwise pursued, in whole or in part, in different States has to be consistent with the principles set out in the Declaration.

When ethical and legal frameworks fail to cover certain blind spots, it could be convenient for individuals or groups to try to cross boundaries in

order to circumvent the application of pertinent laws, rules or regulations. The practice could be effective, but it could also have ethical implications. It could also have undesirable consequences when the outcome of a procedure is not fully satisfactory, especially when responsibility could not be pinpointed.

One important practice that Article 21 does not mention specifically is the migration of health professionals. The movement of health workers to developed countries has been a great concern for a long time, largely because developing countries have seen their health care work force greatly reduced by the 'brain drain.' In many of the source countries, the number of nurses produced by the education system could not match the number of those who have migrated to developed countries. Thus, health care services in developing countries have been rendered inadequate not only in number, but also in quality. The process of recruitment has tended to favour the better-trained and more capable professionals, leaving many of those who are inexperienced to do the job in their home countries.

The migration phenomenon has had the effect of making developing countries pay for the cost of training health professionals who are eventually recruited to serve the needs of people in developed countries. Thus we have the paradox of health care migration – people who are too poor to pay for their own health care are being made to pay for the education of doctors, nurses and other health care providers who serve people in rich countries.

The global situation is not likely to change in the next few years, with the flow of nurses to destination countries expected to increase significantly. Recruitment from lower-middle-income countries and low-income countries will persist. Developed countries such as the United Kingdom, Australia, Canada, Ireland and the United States will be among the top destinations.

Even as the countries involved attempt to improve working conditions for their health care professionals, it should be necessary to institute multilateral agreements to manage the flow more effectively, and to negotiate compensation arrangements between source and destination countries. Policy decisions need to be made at various levels – national, regional and international. It will not help to solve the problems if the countries involved were to look at the issues purely from their own standpoints, imposing their own ethical and legal frameworks. What is required is a transnational approach that takes into account the perspectives of developed countries and developing countries alike.

The approach that is recommended for international research should probably set an example for other transnational practices. Recognizing that migration is a transnational practice with severe ethical implications for source

countries and destination countries alike, the equivalent of an ethical review should be undertaken in all countries involved with the aim of ensuring that the practice is consistent with the principles set out in the Declaration, responsive to the needs of source countries and destination countries alike, and likely to contribute to the alleviation of global health problems. Moreover, it would be useful also to apply to the practice of migration what is suggested in paragraph 4 about international research – that when negotiating an agreement, terms of collaboration regarding benefits should be established with equal participation by those parties in the negotiation.

In general, it should be a good principle to observe that when dealing with transnational practices in general, States involved should attempt to apply to such practices, to the extent possible and reasonable, the provisions of Article 21 that are recommended for international research. After all, the requirements of global justice ought to apply equally whether one is dealing with health migration and organ transplantation or with international health research.

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Chapter 24

ARTICLE 22: **ROLE OF STATES**

Hélène Boussard

Article 22 – Role of States

1. *States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the sphere of education, training and public information.*
2. *States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, as set out in Article 19.*

INTRODUCTION

The Universal Declaration on Bioethics and Human Rights constitutes the core of an original enterprise which merges bioethics and international human rights law to give rise to the 'universal law of bioethics' (Lenoir, 2001). It follows that the determination of the role of States in the operation of the Declaration, which is the object of Article 22, is of first significance to give account of the new ethico-human rights construction. In fact, States are the main actors in international law, while their role is secondary in bioethics. However, at first glance, the traditional paradigm of international law has a great influence on the formulation of the role of States.

Firstly, from the title of the section initiated by Article 22, States are invited to *promote* rather than to *implement* the Declaration. In positivist international law, only binding instruments are to be 'implemented'. Conversely, declarations as resolutions of international organizations are non-legally binding as such and fall in the ambit of 'soft law', which should inform national policies. This precautionary language in the Universal Declaration on Bioethics and Human Rights departs from the terminology used for the previous UNESCO declarations in the field of bioethics.

The Member States have previously adopted a resolution requesting, for example, the *implementation* of the Universal Declaration on the Human Genome and Human Rights (UNESCO, 1999).

Then, Article 22 focuses on the role of *States,* which is in line with the State-centred approach of international law, but not with the intent of the drafters or the traditional approach of bioethics. From here, the provision is under- or over-inclusive depending on the perspective adopted.

Article 22 is under-inclusive insofar as the focus on States departs from the intent of the IBC to give to the Declaration the greatest audience possible. This is flagged by Article 1 on the scope of the Declaration, which points to state and non-state actors. However, the two are not addressed on an equal footing: the State retains its primacy in the promotion of the Declaration and this is precisely what is confirmed by Articles 22 to 24. The apparent discrepancy between Article 1, which carries the intent of the drafters, and Article 22, which is conform with the traditional theory of international law, is not at odds with precedent international human rights law instruments. In fact, 'the Universal Declaration on Human Rights proclaimed as a common standard of achievement for all peoples and all nations, seeks to enlist every individual and every organ of society in a universal human rights movement. This document, as a major product of the UN, assumes that the furtherance and realization of human rights is a task to be carried out at all levels in various ways' (van Boven, 1979: 119). Despite these formulations and laudable claims, positivist theory of international law tells us that there is no intent to recognize the legal personality of the individual. Therefore international human rights law seemingly, and only seemingly, can impose duties on non-State actors (Rosenne, 2004). International norms, in reality, impose upon the State the duty to prohibit or sanction individual behaviour, or to authorize it (Meckled-Garcia and Cali, 2006). In other words, direct and indirect state violations together are said to exhaust the channels through which human rights can be violated. Accordingly, the form of human rights instruments remains unchanged, as does the 'State-centred approach'.

Reversely, Article 22 could be seen as over-inclusive insofar as States are entrusted with the promotion of bioethical principles and the creation of ethics committees, while it is far from clear how much state intervention is desirable in that field traditionally left to non-State actors.

In line with these preliminary remarks, and after depicting the evolution of the article, the comment of Article 22 will first focus on the division of labour between state and non-state actors at the national level. Then, it will explore the contribution of the Declaration in the establishment

of a harmonized regulatory framework at the worldwide level, which is to be realized at national, regional and international levels. As such, the chapter sheds light on the content of Article 22, as well as on the regulatory innovations in the way that the 'promotion' of the Declaration was created.

THE EVOLUTION OF THE ARTICLE

Defining the role of States constitutes the whole logic of an international legal instrument. In that context, a specific article on the role of States is a condition of effectiveness insofar as it gives a more precise account of how States should behave and formalizes more explicitly state moral commitments. Confined to the first paragraph in its original drafting, the provision was progressively extended. In the Third Outline, a paragraph that invited States to 'establish a framework for the assessment and management of risks' was added. As such the provision strengthened the article on risk assessment (at present Article 20 of the Declaration). Finally, the paragraph on the establishment of ethics committees was inserted in the Fourth Outline. It is with these three moral commitments related to the adoption of 'appropriate measures' (para. 1), the creation of ethics committees (para. 2), and the establishment of a process for risk management (para. 3) that the article was presented to the governmental experts in June 2005. Because of States' reluctance to recognize in any manner the precautionary principle, the article on risk assessment was weakened and the corresponding paragraph in the article on the role of States removed altogether during the negotiations. The two other paragraphs remained unchanged and were adopted as such by the UNESCO General Conference.

THE ROLE OF THE STATE IN THE ETHICO-HUMAN RIGHTS 'PROMOTION' OF THE DECLARATION

The newness of the Universal Declaration on Bioethics and Human Rights lies in the fact that its promotion is done not only through legal norms (*lato sensu,* namely legislation and regulation) and 'appropriate measures' (Article 22, para. 1), as for any other international legal instrument, but also through the creation of ethics committees (Article 22, para. 2) at the national, local, institutional and professional levels in accordance with Article 19. This realizes the cross-fertilization of international human rights law and bioethics in the regulation of scientific research. In accordance with the dual 'promotion' of the Declaration, the State is either the regulator, when it adopts 'appropriate

measures', or the 'animator' of a complementary action among regulatory and advisory actors, when it promotes the creation of ethics committees.

1. The State as regulator

The protection of human rights, the promotion of public health and the protection of public order are state prerogatives and most of the provisions of the Declaration fall within one of them. Articles 3 to 10 ensure the protection of the individual in society (e.g. human dignity, benefit and harm, informed consent, privacy, and confidentiality); Article 11 to 16 the protection of communities over time and space (e.g. benefit-sharing, social responsibility, and protection of future generations); and Article 17 the protection of the biosphere. The Legislator, the Executive and the Judiciary constitute the state apparatus and their intervention varies from one country to another. As the protector of individual rights *par excellence*, the Legislator is explicitly addressed only once in the Declaration. In fact, only Article 7 on the protection of the person without capacity to consent refers to 'domestic law'.

The legal approach of paragraph 1 provides a rigid framework that it belongs to the State to adopt. It constitutes only one side of the coin insofar as Article 22 proposes a complementary construction with the creation of ethics committees mentioned in paragraph 2. Fora for debate to operate the consensus-building process, ethics committees allow the necessary flexibility required in a field that is continuously evolving.

2. The State as animator of a complementary action between regulatory and advisory bodies

As to the creation and role of ethics committees, the State is neither the only nor the main actor. In accordance with Article 22, States should 'encourage [their] establishment' and should only establish the framework in which they would ensure the assessment of rules and principles. The formal requirement of independence that governs the composition of ethics committees prevents an intrusive intervention of the State in their composition and operation.

Specific reference to ethics committees had been made in the two previous declarations of UNESCO in the field of bioethics, namely the 1997 Universal Declaration on the Human Genome and Human Rights and the 2003 International Declaration on Human Genetic Data, to control research protocols. In addition, the UNESCO guides on ethics committees complete the three UNESCO declarations (UNESCO, 2005; 2006; 2007). As such, ethics committees are presented by UNESCO as key actors in the regulation

of life sciences. In the terms of Article 19 of the Universal Declaration on Bioethics and Human Rights, their vocation is threefold, namely: promoting ethical reflection in the life and health sciences; fulfilling an advisory role for public and private decision-makers, guiding research workers and practitioners in their actions; and encouraging a broad public debate.

As such, ethics committees appear as new human rights actors and their establishment is promoted in the same way as the creation of ombudsmen and national human rights institutions[1]. They are part of the compliance mechanisms that contribute 'substantially to the realization of individual human rights which makes independent institutions so significant' (Robinson, 1998).

In addition, the creation of ethics committees can be seen as an alternative to human rights mechanisms. In fact, in countries such as China and many African and South American countries, governments are more willing to develop an ethical framework than to enact laws within a human rights framework (Döring, 2004). This preference may be justified by western cultural imperialism usually associated to international human rights law.

TOWARDS A HARMONIZED REGULATORY FRAMEWORK

The Universal Declaration on Bioethics and Human Rights constitutes a building-block for a harmonized regulatory framework at the worldwide level, in which the role of States is strengthened by the role of intergovernmental organizations.

1. The creation of ethics committees as a legal requirement at the worldwide level

The creation of ethics committees has become a legal requirement at the European level and is growingly recognized in international instruments.

At the level of the European Union, the 1995 Directive on Confidentiality, the 2001 Directive on Clinical Trials and the 2003 Directive on Tissues and Cells require the creation of independent committees to ensure respectively confidentiality and privacy, ethical acceptability in clinical trials and management of biological materials and data (European Union, 1995, 2001, 2003).

At the level of the Council of Europe, the Explanatory Report of the Convention on Human Rights and Biomedicine (Council of Europe, 1997), the 2005 Protocol to the Convention on Biomedical Research (Council of Europe, 2005), and the 2006 Recommendation of the Committee of Ministers

on Research on Biological Materials of Human Origin (Council of Europe, 2006a) constitute key instruments in the recognition of the role of ethics committees in the drafting of guidelines, the sensitization of the public to ethical issues, and the independent examination of the ethical acceptability of a research project. It is remarkable that ethics committees are presented as an 'element essential for the protection of fundamental rights' (Council of Europe, 2006b: para. 76).

At the international level, in the WHO documents, ethics committees are entrusted to control the provision that informed consent was adequately obtained in a culturally appropriate way (WHO, 2003). Finally, the 2000 Declaration of Helsinki highlights the role of ethics committees in placebo-control (World Medical Association, 2000).

As a result, the Universal Declaration on Bioethics and Human Rights is in accordance with, and gives account of, the growing obligation put on States to create ethics committees. The instruments mentioned above provide for details on the scope of the mission of ethics committees, which has been expanded and covers now the control of informed consent mechanisms, anonymity issues, access policies (especially unauthorized third party access such as insurers and employers), physical security of data and buildings, and the safety of laboratories.

2. The creation of ethics committees as a multi-level process: the role of intergovernmental organizations in supporting the country level

The role of States in ethics is strengthened and fostered by the activities of intergovernmental organizations in capacity-building and awareness-raising in the field. Intergovernmental organizations, such as UNESCO, do not only work at the harmonization of norms, they also offer at the domestic level the possibilities of training workshops and education programmes, following different modalities (short workshops, academic programmes, distance learning tools, etc.).

In 1993, UNESCO launched its bioethics programme and created the IBC, which is still the sole international and permanent ethics committee at the universal level. The IBC was in charge both of the drafting and of the monitoring of the first bioethics declaration, that is the Universal Declaration on the Human Genome and Human Rights. Conversely, no monitoring process has been accepted by States for the Universal Declaration on Bioethics and Human Rights, which can be seen as a step backward (see the formulation

of Article 25). However, the activities of UNESCO in capacity-building, training in ethics and awareness-raising ensure a form of monitoring of the UNESCO declarations in the field of bioethics at the national level.

In addition, the activities in capacity-building in research ethics of, *inter alia*, the WHO, the Council of Europe and the European Union, constitute evidence of the important role played by international organizations in the field.

CONCLUSION

To conclude, of great significance as to the 'promotion' of the Universal Declaration on Bioethics and Human Rights is the emergence of a common regulatory framework, to which state and non-State actors at national, regional and international levels are invited to participate. The drafting of Article 22 was first presented as over-inclusive and under-inclusive, on the grounds that the State was not the sole actor to be addressed, nor the main actor in bioethics. It appears at the end that the question may be more that of the circumvention of the State entity, given the plurality of actors with similar powers, different composition and *modus operandi*. When ethics committees act as state actors, when hybrid bodies are set up to protect individual human rights, and when international organizations support the country-level, the State appears under different guises. From here, the major future challenge as to the 'promotion' of the Declaration rests in the identification of the players and the co-ordination of their activities.

Endnote 1

See *inter alia* the Recommendation 13(85) of the Committee of Ministers to Member States on the institutions of the Ombudsman (adopted 23 September 1985), (1985) 28 Yrbk European Conv. H.R. 234. Council of Europe, Committee of ministers, Res (85)8 on co-operation between the Ombudsmen of Member States and between them and the Council of Europe (adopted 23 September 1985), (1985) 28 Yrbk. European Conv. H.R. 239. Council of Europe, Committee of Ministers, Res. (97) 14 on the establishment of independent national institutions for the promotion and protection of human rights (adopted 30 September 1997), (1997) 40:2 Yrbk. European Conv. H.R. 612. Council of Europe, Committee of Ministers, Res. (99)50 (adopted 7 May 1999), arts. 3(c)-(d), 5. OAS General Assembly : Support for international exchanges among ombudsmen, OAS AG/RES 1505, XXVII-O/97 (5 June 1997); Support for the work of defenders of the people, defenders of the population, human rights attorneys and human rights commissioners (Ombudsmen) in the context of strengthening democracy in the hemisphere, OAS AG/RES 1601, XXVIII-O/98 (3 June 1998).

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Chapter 25

ARTICLE 23: **BIOETHICS EDUCATION, TRAINING AND INFORMATION**

Giovanni Berlinguer

Article 23 – Bioethics education, training and information

1. *In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well to encourage information and knowledge dissemination programmes about bioethics.*
2. *States should encourage the participation of international and regional intergovernmental organizations, regional and national non-governmental organizations in this endeavour.*

A CHRONICLE OF THE ARTICLE

In 1999, on the right to education, UNESCO and the ECOSOC (UN Economic and Social Council) stated at the outset that education is not only a right in itself but also 'indispensable for the exercise of other human rights' (Joint expert group, 2006: 4). It is regarded as an empowerment right, as a primary vehicle for human beings to participate fully in their communities, and as a means of promoting human rights and democracy.

In 2001 (21–22 October), when the Round Table of Ministers of Science met in UNESCO and encouraged its initiatives in the bioethics field, they recommended that:

> The governments of the Member States and the legislators … must see to it that citizens have an opportunity for informed, pluralistic public debate, and must take into account the various schools of thought, value systems, historical and cultural backgrounds, and philosophical and religious convictions that make up our various societies, … bioethics must be based on the practice of democracy and the active participation of all citizens (UNESCO, 2001).

In 2003, when the UNESCO working group of the IBC presented the first report on the possibility of elaborating a Universal Document on Bioethics, it included a final section, which stated that:

> A universal instrument on bioethics has to call strong attention to the importance of awareness-creation, information, education, consultation, and public debate. These actions are essential and fundamental to the pursuit of all research in this field in a spirit of solidarity, humanity, reason and harmony. And harmony can only exist if fears and questions are taken into account in the drafting of public policies, laws and regulations. This means that the process of elaboration and implementation must be accompanied by an ongoing and transparent public debate, covering both the potential benefits and the hazards of scientific applications (IBC, 2003).

In 2004, the Drafting Group of the IBC was established. In July 2004 a reduced formulation concerning education, training and information was proposed, hasting the States 'to foster all forms of bioethics education at all levels as well as to encourage information and knowledge dissemination programmes about bioethics. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large' (IBC, 2004b). In January 2005 the reference to researchers and members of the ethics committees was omitted, as proposed by the IGBC, and the target of young people was included. The unique comment, formulated in Article 23 by the annexed Explanatory Memorandum, was the following: 'the overall objective of the article is to reinforce and increase the capacities of Member States in the area of ethics education' (UNESCO, 2005). The final text, formulated thereafter and unanimously approved by the General Conference of UNESCO in October 2005, is now included in the Universal Declaration on Bioethics and Human Rights.

FROM PLATO TO KANT

Article 23 substantially considers two main tasks: to foster bioethics education, and to encourage the contributions of all institutions. Other aims and ideas mentioned in the previous documents, summarized in the previous section, like empowerment, pluralistic public debate, taking into account the various schools of thought, bioethics based on the active participation of all citizens, research based on humanity and harmony, were left behind in favour of a top-down methodology. I am convinced that the search of a synthesis is useful

and may be justified, provided it promotes and allows contributions from the bottom, evaluates the existence of different ethics, and faces the difficult task of educating, training and informing on bioethics in the complicated context of human dignity, rights, justice and virtues.

Many philosophers have underlined these difficulties, even before science opened to knowledge and technology new fields for its enormous creative and disrupting potential. Two examples can be provided.

In one of Plato's Dialogues, the scholar Menon asked his master: 'Can you tell me, Socrates, is virtue teachable, or neither a fruit of exercise nor of science, but grows by nature in men, or in some other way?' Socrate's first answer was not very encouraging: 'I would look blissful if you consider me capable of knowing whether virtue is teachable or not, or acquired in some other way. Me! Who is very far from knowing if it is teachable or not, me, who has not a minimal idea of what 'virtue' is!' In the following part of the Dialogue, Socrates added some other considerations, like 'We should take care of ourselves and look for thosewhom, in a certain way, can make us better'. He also suggested that 'real opinions [based upon science] can lead to rectitude of actions no less than intelligence'. Finally he included even the possibility that 'in persons in whom virtue flourishes, it comes from divine destiny' (Plato, 1971: 1253).

The second example is taken from the preface of Immanuel Kant's *Lectures on Ethics*, where he underlined the existence of different fields of the human free will:

> The science of the rules according to which man must act is the practical philosophy [ethics], while anthropology is the science of the rules of his actual behaviour. One and the other are strictly connected, and ethics cannot exist without anthropology, because the knowledge of the subject, and of his capability to do what is pretended by him, is a prerequisite (Kant, 1971: 4–5).

He added that the tautological repetition of the rules is like 'an empty sermon', and that the knowledge of man, therefore, is necessary 'to evaluate what he can make'.

WHICH BIOETHICS?

In a few decades, bioethics became one of the most promising fields in moral philosophy, invaded the media, constituted a common reference for academic debates and daily conversations for common people, and a top

and often a difficult issue on the agenda of parliaments, governments and international agencies. We should try now, in our rapidly changing and multilaterally globalizing world, to work in two related fields. The first is the recognition of different ethics, whose existence can be considered one of the bases of the human freedom, rather than an obstacle. The second is to stimulate the creation of a *common sense* in relation to the progress of science and ethics.

This process can go through the *frontier bioethics*, which covers the last (and future) development in biomedical sciences and in professional activities, which up to now were impossible and even inconceivable, like IVF, organ transplantation, gene therapy, use of stem cells, nanotechnologies and so on. This same process, with different methods, can go through the *everyday bioethics*, which concerns the bioethical and social choices of common people facing persistent and critical elementary conditions of their life. The two mentioned fields cannot be separated, neither in theory nor in practice.

On the contrary, they are strictly connected, like in health, where extraordinary results are achieved but the majority of mankind cannot reach them. This issue was clearly presented in the first draft of the Declaration:

> Health as a dual moral value: it is essential for the quality of life and life itself, and is instrumental as a precondition of freedom. When disease prevails, the destiny of a person (and even of a nation) is left to external factors and powers, and may enter in an irreversible vicious circle of regression. The inequality between the rich and the poor – at level of individuals, communities and nations – is becoming increasingly felt in the area of health and health care, thereby contributing to the despair and injustice that prevails, and continue to increase in other health-related fields as food, income and education (IBC, 2004a).

FROM WHOM, TO WHOM AND HOW TO TEACH AND LEARN BIOETHICS?

If education has to be addressed 'in particular to young people', a sharp distinction of roles between who teaches and who learns is doubtful, particularly in a field where the different actors are influenced by feeling, sensations, opinions, and often personal or familiar experiences. The first who has to learn is the teacher, also because the students often consider him/her for what he/she does, more than what he/she says. Their mind is not a *tabula rasa*, a complete blank. It is influenced by friends of the same age,

families, ideologies, religions, media, public and private behaviours of famous persons. Knowing and understanding these various sources, the teacher can stimulate a critical attitude; can help the learner to build his/her own system of information, behaviours and values; can make it possible for them to fulfil better their professional duties in connection with other professionals and the community. Experience has shown that many local ethics committees can play an important role in bioethics education.

The question 'how to teach and learn' may have as many possible answers as the variety of positive experiences. They should preferably be curricular, interdisciplinary, and continuous. It is necessary to give clear and precise information; to go through facts and ideas, in order to show the long and lasting efforts to distinguish good and evil, just and unjust; to raise awareness on the implications of any decision on persons and society; and finally to stimulate the development of a 'democratic bioethics'. This expression does not mean political interference or voting on ethical choices, but promoting a higher consciousness of citizens and building a citizenship in relation to bioethics.

A high level of transparency is necessary around the benefits, limits and risks of biomedical sciences and technologies. Moreover, the idea of informed consent should be revised in order to avoid a self-defensive attitude of professionals, to criticize bureaucratic interpretations, and to help the citizens to make conscious choices. Finally, it is important to stress the importance of clear and accessible language in communicating facts and ideas.

Bioethics education and bioethics itself will develop and will be observed with transnational eyes in a future that has already begun. It is already happening as a growing number of scientific and professional practices, as well as many norms and rules, have extended beyond borders, like the import-export of embryonic and stem cells, organs, tissues and body cells, DNA samples and genetic data. Many biomedical researches and experiments involve several countries, expanding the benefits of knowledge but often putting avoidable burdens on poor people or creating new forms of exploitation. Moreover, positive actions for health and welfare are undertaken through international co-operation, because global risks demand global answers. Many universal declarations have been confirmed by consensus and often by results, and must now be confronted and enriched by the plurality of values and interests, existing in all parts of the world. This implies also the development of a mutual and reciprocal education, in bioethics and in any other field.

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Chapter 26

ARTICLE 24: **INTERNATIONAL COOPERATION**

Ousmane Blondin Diop

Article 24 – International cooperation

1. *States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.*
2. *Within the framework of international co-operation, States should promote cultural and scientific co-operation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.*
3. *States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.*

BACKGROUND OF THE ARTICLE

Humanity has always needed ethics. Every human society and each according to its situation has always been concerned about moral values and ethical principles to guide individual behaviours and to regulate life within a community. The philosophy of Spinoza, Kant and different thinkers and philosophers of the subsequent centuries have contributed to the construction of universal values based essentially on the intangible foundation of human dignity.

The long history of the relation between science and ethics, since the famous citation from Rabelais ('Science without conscience is nothing but a ruin of the soul') confirms the need of ethics for humanity.

The world is transforming from a recent innovative past towards an uncertain future. In a 'Sartrian' context, this uncertain period is critical in the

face of more and more astounding scientific advances and facts. Following this state of affairs, the international community cannot rely solely on ethical and professional codes of conduct to govern the relations between scientists and workers of all disciplines.

Resources exist to create the conditions for minimal prosperity everywhere in the world. However, numerous barriers also exist that endanger the ability of the planet to sustain human life. Therefore humanity lives with the strange and uncomfortable feeling of a stringent cohabitation between progress and social chaos. The adoption of the Universal Declaration on Bioethics and Human Rights precisely aims at injecting principles agreed by everyone in this ever-changing world, and thus to try to bridle it.

THE EVOLUTION OF THE ARTICLE

Already in the first meeting of the Drafting Group of the IBC in April 2004, reference was made to international co-operation as a means of implementing and promoting the Declaration (IBC Drafting Group, 2004). An elaborated text appeared for the first time in the Second Outline of a Text (IBC, 2004a). In the Section on Promotion and Implementation, an Article is proposed on Solidarity and International Co-operation:

> a. States should respect and promote solidarity towards individuals, families, populations and groups, with special regard for those rendered vulnerable by health or other personal, societal and environmental conditions and those with the most limited resources.
> b. States should foster the international dissemination of scientific information and make every effort to guarantee the free flow and sharing of scientific and technological knowledge [namely throughout the creation of research and education structures in the developing countries as well as the transfer of technology].
> c. In the framework of international co-operation, States should promote cultural and scientific co-operation, endeavouring to enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge and of the related know-how (IBC, 2004a).

The text of the draft article remained unchanged in the Third Outline of August 2004 (IBC, 2004b). In the Fourth Outline of December 2004 some

changes were made. First, the components of the article were reordered. Part b) became the first Part a) of the article. Part c) in the Second Outline became Part b) in the Fourth Outline, while Part a) changed to Part c) (IBC, 2004c). This is essentially the same order as in the final adopted Declaration. Secondly, minor textual changes were introduced. In the Fourth Outline, in the new Part b) (former Part c) the text 'and the benefits thereof' was added at the end of the sentence. In the new Part c) (former Part a) several changes were made:

> a. States should respect and promote solidarity between and among individuals, families, groups and communities, with special regard for those rendered vulnerable by diseases or disabilities or other personal, societal or environmental conditions and those with the most limited resources.

No changes were introduced in Part a) (former Part b); at this stage the text still has the bracketed sentence. The Preliminary Draft Declaration, issued by the IBC a few months later in February 2005, presents the text as it is in the finally adopted Declaration. A few changes were made compared to the previous Fourth Outline. First of all, the title was changed into: International Co-operation. The question of solidarity was addressed in a separate article in the Declaration, so that the focus of the present article could be on international co-operation. Secondly, the bracketed text in Part a) of the article was removed. Except for a minor textual change ('Within the framework' instead of 'In the framework') Part b) was the same. In Part c) the only change made was 'diseases or disabilities' to 'disease or disability' (IBC, 2005).

The final text of the article adopted by the IBC was approved in its original formulation by the governmental experts in their second meeting in June 2005 (Report expert meeting, 2005), and therefore became part of the final Declaration.

WHAT DOES THIS MEAN?

After the Industrial Revolution, the mastering of new technologies has resulted in unlimited progress in science and technology. The new technologies have considerably transformed the life sciences like never before. Humankind has nearly succeeded in understanding the genetic language. After the discovery of the DNA double helix, human beings have learned to 'read life', then they learned to 'write life' by isolating and creating genes. Afterwards, they started to 'correct life' by repairing errors of nature, for example birth defects.

But today, humankind is capable of recomposing animal and plant species or even transforming the human species. The mastering of genetics has provided human beings with a novel and formidable power. However, domestic, parent-children, family, state relationships and the social, human, political and legal architecture that has been at the base of human relationships have been disrupted.

Since human beings, family, society and time have been affected by this formidable revolution, the international community should collectively reflect on the issues and on our common responsibility towards the future of the human species.

UNESCO has naturally been charged with conducting intergovernmental reflection and negotiation of a declaration, and not a convention, principally aimed at States and other stakeholders that acknowledges freedom of research in the framework of ethical principles of human dignity, human rights and fundamental freedom.

The drafting and elaboration of such a declaration aimed at filling a void in the international arena around a highly technical challenge. This also required that the Declaration present a universal normative framework as well as ensuring its application. Hence the relevance of the article dedicated to international co-operation.

APPLICATION

In order to universally promote the principles of the Declaration, States are invited to support international co-operation so as to reinforce the capacities of developing countries.

During the discussions and the cycles of adoption of the Declaration, it appears that the reflection around bioethics was primarily focused on the exigencies of developed countries, but the agenda of the debate was of course much wider. In fact, international events were regularly relating stakes and issues posed by life sciences: medical assistance for reproduction, artificial insemination, freezing of sperm in test tubes; freezing of embryos for 99 years; transplantation and the risk of commodification; and questions concerning the end of life, cloning for therapeutic purposes and for reproduction.

On the other hand, challenges of developing countries are related to the issue of greater access to scientific knowledge, the sharing of knowledge, the struggle against pandemics due to scientific progress, the acquisition of knowledge and scientific discoveries, brain drain, the reduction of the gap with developed countries, the termination of biopiracy, and the assurance that

research protocols for studies with human beings are focused on the benefits for the participants themselves who can no longer be considered as means for research because of their vulnerability. These questions have enriched the debate and the Declaration by considering the emerging problems and placing them at the centre of the indispensable international co-operation to be established.

In light of the issues at stake, urgent despite their apparent distance, only duly intelligibly thought-out international co-operation may enable a declaration as opposed to a convention to operate and produce beneficial actions for all.

Therefore, the nature, structure and content of such co-operation needs to be defined in order to achieve the objectives of the Declaration. Co-operation means working together. Therefore priority should be given to debates between States and stakeholders to agree on the objectives of such a co-operation, for example to share existing and indispensable technologies, to fight against hunger and disease, and to regulate the conservation of ova. The principal objective to promote and apply the Declaration by collaborating together should be at the base of all co-operation.

The debate between researchers, scientists, politicians and philosophers has to be universal to prevent exclusion between and within countries. It is the continuous debate that can guarantee the free circulation of scientific knowledge in order to rectify and prevent disequilibrium between consuming and exporting countries.

Training and teaching of ethics are the essential tools for reinforcing the capacities of developing countries and thereby preventing them from staying dependent on patents and discoveries emanating from developed countries.

It would be timely and original to envisage co-operation in terms of the participation of local communities in a micro-collaboration perspective and the development of local research that takes into account the cultural environment. This new partnership based on a much closer collaboration between scientists and the community, that is the research subject, will favour new relationships based on trust and not solely on exploitation. Co-operation aimed at research at the local level may provide indigenous solutions that can be geared to wards attending to social emergencies and development.

The Declaration can therefore provide a normative framework that can serve as a dynamic compromise between scientists and populations concerned, while at the same time respecting the principles of freedom, social responsibility, informed consent and, why not, transparency and accountability.

UNESCO, in its role of promoting the Declaration, has to initiate and incite such co-operation. Therefore, UNESCO has to become the agency that facilitates the emergence of new paradigms other than the logic of the market and commercial regulations, and moreover that makes sure that scientific discoveries do not become objects of disputes between (double standards) and within countries. It is under this condition that UNESCO will have worldwide support in favour of ethics and will become the natural authority serving all as it will be recognized by all: States, scientific communities, populations concerned and the individual citizens. International co-operation in ethics has to be regarded as an investment in the human being, and not as research to reap benefits following discoveries. This dimension of the Declaration has to be asserted as a priority right at the beginning of its application and will justify UNESCO's full engagement in accordance with its mandate.

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Chapter 27

ARTICLE 25: **FOLLOW-UP ACTION BY UNESCO**

Nouzha Guessous Idrissi

Article 25 – Follow-up action by UNESCO

1. *UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).*
2. *UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.*

WHY IS THE ARTICLE IN THE DECLARATION?

By adopting the Universal Declaration on Bioethics and Human Rights during the 33rd session of the General Conference of UNESCO, Member States have *de facto* agreed on the principles therein and have recognized their universal character. This implies their solemn commitment to its implementation and to the necessary measures to be taken to sustain the Declaration, although this international instrument is of declarative nature and therefore not binding.

In fact, the initial proposal of the then French president was to elaborate a convention on bioethics. Thereafter, the mandate given to the IBC by Member States was to elaborate 'a Declaration on Universal Norms on Bioethics'. But conscious of the difficulties of having a consensus from States on binding norms on bioethics, the IBC proposed instead the elaboration of a declaration containing universal principles, including articles on the implementation and follow-up, measures that would give it an important and significant weight in the international arena. In fact, the principal example of the strength of a declaration is the Universal Declaration of Human Rights adopted in 1948, whose weight and normative historical importance is illustrated by the numerous written and revised national constitutions explicitly

referring to it, although it does not have a binding character. Furthermore, it is also worth mentioning that provisions of the Universal Declaration on the Human Genome and Human Rights adopted in 1997 and the International Declaration on Human Genetic Data adopted in 2003 have been cited and utilized by many countries during the process leading to the elaboration of national legislation on human genetics.

Therefore it implies that the provisions of the Universal Declaration on Bioethics and Human Rights had to identify the measures that UNESCO and its statutory organs IBC and IGBC had to put in place in order to strengthen the successes of the implementation and the impact of the Declaration.

This was in line with previous history concerning resolutions of the United Nations System and other organizations. Hence Resolution 20 C for the implementation of the Declaration on Race and Racial Prejudice of 1978 invites the Director-General to 'prepare a comprehensive report on the world situation in the fields covered by the Declaration on the basis of the information supplied by Member States' and to 'present his report to the General Conference and to submit to it for decision' (UNESCO, 1978). Moreover, the resolution adds that the report might also be based on other information such as reports of NGOs or institutions and organs of the United Nations System and other international organizations, and that it is the responsibility of the Director General to appreciate the credibility of these organizations, to commission the reports and at the same time to define the methods and modalities of collection.

Another innovation has been introduced in the Universal Declaration on the Human Genome and Human Rights adopted during the 29th session of the General Conference of UNESCO (16 November 1997) concerning the recognition of the role of the IBC in its follow-up (Article 24). In fact, this article asks the IBC to contribute: 'to the further examination of issues raised by their applications and by the evolution of the technologies in question' in order to 'make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference, and give advice concerning the follow-up of this Declaration'; a role that has been confirmed by the resolution concerning application 29 C/17 (UNESCO, 1997) and 30 C/23 (UNESCO, 1999). In addition, resolution 29 C/17 invites the Director-General to prepare a comprehensive report on the application of the Declaration on the basis of the information supplied by Member States and any other information supported by trustworthy evidence (UNESCO, 1997).

A supplementary step has been taken by the International Declaration on Human Genetic Data adopted on 16 October 2003. It is stipulated in Article 25 that 'the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration' and that 'the two Committees should be responsible for its monitoring and for the evaluation of its implementation, *inter alia*, on the basis of reports provided by States'. Therefore, the IBC and the IGBC were assigned the responsibility of evaluating the implementation of the Declaration based on reports provided by States and to formulate any opinion or proposal addressed to the General Conference, to further the effectiveness of this Declaration in accordance with UNESCO's statutory procedures. Furthermore, the resolution concerning the implementation of the Declaration 'Calls upon Member States to notify the Director-General regularly of any pertinent information on steps taken by them to implement the principles set forth in the Declaration' and 'invites the Director-General (…) to report to it at its 33rd session on the implementation of this resolution', that is in 2005.

Overall, the two examples illustrate UNESCO's willingness to provide more specific guidelines to Member States following the proclamation of declarative instruments and thus guaranteeing effective implementation; and to involve the IBC and the IGBC in the promotion, follow-up and implementation activities.

Having that in mind, the Drafting Group put in place to prepare the Declaration took the time to identify specific steps that had to be taken to properly implement this instrument. It is for that reason, as it has been the case with the two previous bioethics declarations, that, from the beginning, IBC has integrated follow-up activities that were submitted to the meeting of governmental experts, within the framework of articles related to promotion and implementation, along with other education actions, training and information, role of States, exclusion of actions opposed to human rights, fundamental freedoms and human dignity.

PROCESSES AND PHASES OF ELABORATION

It is in fact in the second draft, and the following drafts, that a subdivision into two articles of the implementation measures has been introduced, one relative to the roles of IBC and IGBC and the other relative to the follow-up action of UNESCO. This subdivision remained in the following drafts of the Declaration and has been finalized by the IBC at its extraordinary session

of 28 January 2005. The fourth draft Declaration was then submitted to the meeting of governmental experts, and to the Executive Board before being adopted at the 33rd General Conference of UNESCO.

(a) The roles of IBC and IGBC

Hence the IBC and the IGBC have been given roles that are fairly similar to the ones given to them in the International Declaration on Human Genetic Data, that is to contribute to the implementation and the diffusion of the principles within the Declaration. But the major novelty is the proposal to institutionalize the regular reporting from the Member States to the Director-General. According to Article 27(b) of the draft, ' Reports provided by States, on the steps they have taken, whether of a legislative, administrative or other character, to give effect to this Declaration, should be addressed every five years to the Director-General of UNESCO'.

It has to be noted that this innovation is a major one and may seem restrictive for Member States as the first article gave a broad definition of bioethics including not only ethical questions posed by medicine and health sciences, but also questions posed by social sciences when applied to human beings. Moreover, the Drafting Group had proposed a periodicity in the submission of the reports.

Therefore, since the second draft of the Declaration, the article states that 'on a collaborative basis, the two Committees *should* be responsible for its monitoring and for the evaluation of its implementation, in particular on the basis of reports provided by States.' Therefore the Drafting Group was vesting in the IBC the duty to oversee and evaluate reports that states were to be asked to prepare every two years. According to paragraph (b) of the article, the tasks of the IBC were as follows: 'after having examined the reports, IBC will advise following the statutory procedures of UNESCO'. Thereafter the task of the IGBC was proposed as follows 'after examining the opinion of the IBC and the reports provided by the states, the Intergovernmental Bioethics Committee will communicate its own advice to the Director-General so that he transmits it with the advice and the recommendations of IBC to Member States, the Executive Board and the General Conference'. Therefore, the IBC and the IGBC, in consultation and based on reports from states, should formulate advice, proposals or recommendations to the attention of the General Conference. These provisions were maintained in the following drafts, including the one that was submitted to the governmental experts. It has to be noted that there were differences between the drafts in the tense

of verbs when considering 'the obligation' of states to provide reports. They varied between 'shall', which is an obligation, and 'should', a facultative option.

The other substantial innovation compared to Article 25 of the International Declaration on Human Genetic Data was the periodicity of reports. The initial period of reporting in the first three drafts of the Declaration on Bioethics was every two years, while it became every five years from the fourth draft, and this was maintained up to the final draft. The extension of the period between reports was motivated by the difficulties experienced in obtaining and harmonizing reports, and by the time needed to prepare an effective evaluation of actions undertaken by States in accordance with the procedures of UNESCO.

Finally, all drafts of the Declaration elaborated after extensive consultations with the IGBC, Member States, national, regional and international institutions and organizations gave a substantial role to IBC and IGBC for the promotion, follow-up and implementation of the Declaration, and this role was spelled out in a specific article. It is in fact during the process of discussion of the draft by representatives of States that the reporting process from the Member States suggested by the IBC was eliminated. Furthermore, the point concerning the role of IBC and IGBC has not been maintained as a separate article, but included in Article 25 that says: 'UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).' This could be seen as a weakening of the role of the two committees in the follow-up action.

(b) The follow-up activities of UNESCO

These activities had been envisaged by the Drafting Group in line with the provisions of Article 26 of the International Declaration on Human Genetic Data, which states the role of UNESCO in promoting the advancement of life sciences and technologies while respecting human dignity, human rights and fundamental freedom. Hence, since the second draft of the project on the Declaration on Universal Norms on Bioethics, two supplementary paragraphs had been elaborated concerning other activities specifically related to the role and scope of the Declaration.

In the section on follow-up action by UNESCO, paragraph (b) addressed the role that UNESCO should play in the promotion of bioethics

in relation to the environment according to the scope of the Declaration as stipulated in its first article. It was suggested that 'UNESCO shall reaffirm its commitment to dealing with all aspects of the biosphere and, if necessary, shall elaborate guidelines and international instruments, as appropriate, on ethical principles related to the environment and other living organisms.'

This paragraph brought an alternative option to the debate that had happened in the IBC as well as during the consultation process, on the scope and the issues to be covered by the Declaration. Ethical questions relative to other forms of life, the environment and the biosphere were in fact extensively discussed and finally included as being the responsibility of human beings. This appears in the Preamble of the Declaration (para. 11 '*Aware* that human beings…') and in the first article that extends the scope of the Declaration to environmental dimensions of ethical questions. This paragraph was maintained in the following three versions and therefore was present in the final draft of the Declaration submitted to governmental experts for examination.

Paragraph (c) brought another important innovation, since it planned a re-examination of the Declaration five years after adoption and periodically afterwards, in light of scientific and technological developments. This has to be carried out in accordance with the statutory procedures of UNESCO; part of which has been stated in the second draft of the article relative to the roles of IBC and IGBC. This was justified by the fact that, for bioethics, a revision mechanism is essential to evaluate and update the content of the Declaration, hereby ensuring its effectiveness and relevance. It has to be noted that such a mechanism has already been adopted in the European Convention on Human Rights and Biomedicine, as well as in some national legislations.

It is in this spirit that, following consultations and hearings, the third draft added a fourth clause. Paragraph (d) of Article 27 stated:

> With respect to the principles set forth herein, this Declaration could be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO's statutory procedures.

Consequently, UNESCO was invited to consider moving from a non-binding to a binding instrument. This clause was maintained in the following versions up to the final draft submitted to governmental experts.

Finally, at the end of the process, the Preliminary Draft Declaration finalized by the IBC at the Extraordinary Session of 28 January 2005 included two separate articles: Article 27 on the roles of IBC and IGBC,

and Article 28 on the follow-up activities of UNESCO. These two matters were put together during the second meeting of Governmental Experts in Article 25 of the adopted Declaration.

MEANING OF THE ARTICLE

As stated in the text of this Article, the follow-up activities of the Declaration have focused on the diffusion and promotion of the principles proclaimed in the Declaration, doing away with the reporting and revision processes suggested by the IBC. This Article reaffirms the principle of seeking help and assistance from IGBC and IBC without specifying the extent of their role – as compared to the two previously adopted declarations on bioethics.

The adopted version of this Article reaffirms the will of UNESCO to tackle bioethical questions and to promote co-operation between the IBC and the IGBC. This recommendation, in line with the nature and status of the two committees, can be considered as recognition of the effectiveness of that co-operation during the elaboration of the Declaration. In fact, this process is recognized as having been transparent owing to the extensive consultations on the successive drafts with the IGBC, as well as with national, regional and international bodies. Furthermore, the fourth session of IGBC (24 and 25 January 2005) had examined the Fourth Outline of the Declaration, and provided recommendations that were re-discussed during the joint session of IBC and IGBC on 26 and 27 January 2005. It was on 28 January 2005 during an Extraordinary Session that IBC finalized and adopted the Preliminary Draft Declaration that was submitted to the governmental experts.

APPLICATION OF THE ARTICLE

Since the adoption of the Universal Declaration on Bioethics and Human Rights in October 2005, the Division of Ethics of Science and Technology and the IBC have implemented numerous activities:

– Translation, publication and diffusion of the Declaration; the adopted text has been available from the start in the six official languages of the Organization (Arabic, Chinese, English, French, Spanish and Russian). Furthermore, the text has been translated into 24 national languages, namely Armenian, Azeri, Basque, Bulgarian, Catalan, Croatian, German, Georgian, Greek, Hebrew, Hungarian, Italian, Japanese, Korean, Latvian, Macedonian, Norwegian, Persian, Polish, Portuguese, Romanian, Thai, Turkish and Vietnamese.

- Presentation of the Declaration by Members of IBC and staff of the Division of Ethics of Science and Technology of UNESCO at different national, regional and international conferences. The Declaration has been the subject of lectures and presentations at more than 60 national, regional and international conferences and seminars organized in different countries all over the world at the initiative of the Secretariat, by Member States, NGOs or local bodies active in the field of bioethics (including in Argentina, Australia, Belgium, Brazil, Canada, China, Colombia, Denmark, the Dominican Republic, Egypt, Fiji, Finland, France, Germany, Greece, India, Israel, Italy, Japan, Kazakhstan, Kenya, Mexico, the Netherlands, New Zealand, Peru, the Republic of Korea, Romania, Saudi Arabia, Slovakia, Spain, Sri Lanka, Togo, Trinidad and Tobago and the United Kingdom).
- Likewise, the Declaration was reproduced and commented upon in many specialized journals. Books have also been published focusing on the Declaration. Moreover, the Declaration has become a legal reference, as testified on two occasions: first, within the United Nations system during the intergovernmental negotiations for the elaboration of the draft international convention for the protection and promotion of the rights and dignity of persons with disabilities; and second, when the European Court of Human Rights had to rule on a case related to the implantation of embryos fertilized *in vitro*.
- The provisions of the Declaration are furthermore promoted by UNESCO's Global Ethics Observatory (GEObs) – a system of databases available in UNESCO's six official languages and freely accessible online, with worldwide coverage of bioethics and other areas of applied ethics in science and technology, such as environmental ethics and science ethics. The Observatory now includes five databases: Database 1: Who's Who in Ethics; Database 2: Ethics Institutions; Database 3: Ethics Teaching Programmes; Database 4: Ethics-Related Legislation and Guidelines; and Database 5: Codes of Conduct. There are currently over 1,000 ethics experts in Database 1; over 200 ethics institutions in Database 2; over 170 ethics teaching programmes in Database 3; and over 140 codes of ethics in Database 5. Database 4 has legal instruments from Brazil, Ethiopia, Hungary, Japan and Jordan, while information will be entered soon from Australia, Egypt, Germany, Israel, Panama, South Africa, and the South Pacific island states. A large amount of data in Database 3 and Database 4 is now available in English, French and Russian, with plans

for further translation into Arabic, Spanish and Chinese. Activities to expand and improve the system are planned for 2008.

– The Ethics Education Programme (EEP) aims at initiating and reinforcing educational activities in Member States through various phases: (a) assessing the infrastructure for developing and implementing teaching programmes, (b) developing and promoting teaching programmes, and (c) developing educational resources for implementing programmes. Since the adoption of the Declaration, mapping of experts in ethics teaching and sampling of teaching programmes have been pursued through regional expert meetings organized in Budapest (Hungary, 2004), Moscow (Russian Federation, 2004), Split (Croatia, 2005), Muscat (Oman, 2006), Tehran (Islamic Republic of Iran, 2006), Istanbul (Turkey, 2007) and Marrakech (Morocco, 2008). Ethics teacher-training courses have also been organized in co-operation with the UNESCO Chair in Bioethics in Haifa (Israel), in Bucharest (Romania, 2006), at the Egerton University (Kenya, July 2007), in Bratislava (Slovakia, September 2007) and also in Riyadh (Saudi Arabia, November 2007). Lastly, the proposal for a core curriculum in bioethics, based on the principles of the Universal Declaration on Bioethics and Human Rights, is in the process of being finalized by an *ad hoc* committee of experts (from IBC, COMEST, UNESCO Chair in Bioethics, the Academy of Sciences for the Developing World (TWAS) and the World Medical Association (WMA). The Committee met in Paris in July 2005, March 2006, June 2006, August 2006 and July 2007 to discuss the draft proposal. Finally, a consultation meeting on the draft proposal took place in Paris on 4 and 5 July 2007 in co-operation with TWAS. Twenty-four experts (from Argentina, Brazil, Cameroun, Canada, India, Indonesia, Kenya, the Netherlands, Nigeria, Oman, Pakistan, the Philippines, Qatar, South Africa, Surinam, Togo, the United Arab Emirates, and the United Kingdom) were invited to provide feedback on the draft proposal. On the basis of the feedback and comments, the Advisory Committee revised the proposal in July 2008 so that the final version can be made available later in 2008.
– Through the Assisting Bioethics Committee project, UNESCO continues its efforts to assist Member States that so wish (in particular developing countries) in establishing and/or reinforcing national ethics committees. Three guidebooks on national bioethics committees have been published and disseminated, and two teams of experts with practical experience in bioethics committees set up to give technical support, appropriate working

methods and operational procedures to Member States. Preparatory work has begun in co-operation with Togo, Malawi, Ghana, Jamaica, Madagascar, Mauritius and Gabon. Several other Member States have also requested UNESCO's assistance and support.

Finally the collaboration between IBC and IGBC has been maintained as prior to the adoption of the Declaration.

CONCLUSION

The analysis of the process of elaboration of Article 25 on the follow-up of the Universal Declaration on Bioethics and Human Rights, from an historical context of normative activities of UNESCO in general and in the field of bioethics in particular, shows a weakening of the commitment of States in the promotion and implementation of the Declaration, as well as a weakening of the role of IBC and IGBC in the follow-up activities. However, bioethics remains the priority of the programmes of UNESCO, and this was confirmed during the 33rd and the 34th General Conference. Hence there is hope that a resolution for the implementation of the Universal Declaration on Bioethics and Human Rights will specify and reinforce the follow-up mechanisms and the role of IBC and IGBC. Finally, it should be noted that, at the end of its 12th session in December 2005, the IBC, in its recommendations, proposed to the Director General to consider the presentation of the Universal Declaration on Bioethics and Human Rights at the General Assembly of the United Nations in view of its endorsement, as was the case for the Universal Declaration on the Human Genome and Human Rights; this would significantly reinforce the weight of this important and historical Declaration.

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Chapter 28

ARTICLE 26: **INTERRELATION AND COMPLEMENTARITY OF THE PRINCIPLES**

Eugenijus Gefenas

Article 26 - Interrelation and complementarity of the principles

This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

INTRODUCTION

The Article presents all the 15 ethical principles listed in the Declaration (from Article 3 to Article 17) as complementary and interrelated. It also says that each principle is to be considered in the context of the other principles. In this short commentary to the Article we will try to answer the following questions:

- What is the meaning of the article and its key concepts?
- What is the place and role of the article for the bioethical discourse at both academic and policy-making levels?
- How should the article be interpreted in the context of the whole Declaration as well as in relation to other relevant bioethics guidelines and bioethical literature?

While trying to provide answers to these questions, we will also give some examples of possible applications of the Article.

First of all it should be pointed out that this article has a paramount importance for the Declaration because it addresses a fundamental methodological issue of bioethics, namely, it reflects the very nature of the moral discourse, which is based on the plurality of different interrelated moral perspectives complementing each other (sometimes also coming into conflict with each other!) and in that way composing a complex picture of moral reasoning. In other words, Article 26 stressing the complementariness of the 15 interrelated normative ethical principles might be seen as a guiding rule

on how to understand the ethical debate and to develop it, as well as a way to seek solutions to complex bioethical problems.

MORAL DISCOURSE AS INTEGRATION OF SPECIFIC MORAL PERSPECTIVES

Each of the 15 ethical principles listed in the Declaration might be seen as capturing some specific and different features of the moral discourse. For example, even thinking about such a traditional and widely discussed issue as the ethics of a health care provider-patient relationship, we have to refer to different ethical principles reflecting different ethical aspects of such a relationship. We cannot provide a full picture of a doctor-patient relationship without referring to such ethical principles as a positive benefit/risk ratio, respecting autonomy, privacy and confidentiality, and seeking free and informed consent for any medical intervention on the patient. All the ethical principles should be followed and all the values behind the principles respected, because this is the only way to reach a morally satisfactory therapeutic relationship.

Building the doctor-patient relationship exclusively on one ethical principle leads to a reductionist approach. For example, building the doctor-patient relationship exclusively on the principle of beneficence or maximization of benefits to the patient leads to an unjustified paternalism. On the other hand, overstressing the role of personal autonomy and informed consent might lead to the practice of 'consumerism', when a doctor ignores important aspects of care of the vulnerable patient unable to understand distressful information. What is more, an ethically relevant picture of the doctor-patient relationship should also encompass a broader perspective of protection of the third parties as well as considerations for social justice. Think, for example, about the prevention of communicable diseases or the necessity to ration scarce health care resources – situations that so often arise in modern health care. These situations urge a health care practitioner to think not only in terms of so-called individualistic ethics based on the moral perspectives reflected in such concepts as benefit and harm, autonomy, consent, privacy and confidentiality; they also demand broadening the moral perspective to encompass social ethics expressed in terms of social justice, equity or social responsibility.

That is why we could claim that this Article of the Declaration stressing the importance of interrelation and complementarity of the bioethical principles captures an essential feature of the moral discourse. This discourse

develops by integrating different moral perspectives and the ethical principles that might be seen as their summaries. Bioethical principles are also closely interrelated, because complementing each others' perspective they provide a comprehensive and rich picture of ethical reflection on a particular issue.

EVOLUTION OF THE ARTICLE

Even if the article on the interrelation and complementarity of the principles appears only in the Fourth Outline of the Declaration, the general idea behind it were expressed at the earlier stages of the development of the instrument. The need to avoid any hierarchization of principles was expressed during the very first meeting of the Drafting Group of IBC, which took place on 30 April 2004 (IBC Drafting Group, 2004a). However, in the first three outlines of the text, the principles were in fact hierarchically grouped under different titles. For example, the Third Outline categorized principles as General/ Fundamental, Derived and Procedural. It should be noted that the Third Outline also contained Article 28: 'Interpretation' and already expressed the ideas of interrelation and complementarity when stating that principles of the 'Declaration are interrelated and each principle should be construed in the context of other principles' (IBC, 2004a). This discrepancy was addressed during the sixth meeting of the Drafting Group in December 2004. The report of this meeting states that even if the distinction between 'fundamental' and 'derivative' principles seems to be appropriate from a theoretical point of view, the consultation process showed that this 'could lead to the confusion as to a possible hierarchization of principles' (IBC Drafting Group, 2004b). That is why, in order to stress the plurality of moral perspectives and avoid the hierarchization between the principles, the Fourth Outline of the text regroups them under a single section 'general principles' and explicitly introduces interrelation and complementarity in Article 4 (IBC, 2004b). As this is in fact the principle addressing the methodology of moral reasoning, it has been moved to the section on Final Provisions and became Article 26 in the final version of the Declaration.

RESOLUTION OF MORAL DISAGREEMENTS: BALANCING NON-HIERARCHICAL ETHICAL PRINCIPLES

It is important to note, however, that even if complementariness and interrelatedness are important features of the 'functioning' of the bioethical principles, we have to be aware of other closely related conditions/features of the relationship between bioethical principles implicit in the Declaration,

namely, the pluralistic and non-hierarchical character of the relationship between the principles. The non-hierarchical relationship between the principles offers multiple solutions to bioethical problems. It also very often leads to controversial interpretations of the moral issues. The discussion on the controversy between personal autonomy and paternalism clearly reflects this feature of the complex relationship between ethical principles. The principles not only complement each others' moral perspective; they may also come into a deep value conflict when interpreting a particular case. Such a value conflict was at the centre of the shift from a traditional medical ethics to modern medical ethics. That is why the conflict between the principles reflecting different moral perspectives is another fundamental feature of the moral discourse, which should be taken into account when explaining the Article. It also helps to explain why these principles should be balanced in each particular case and in each different socio-cultural context. For example, even if modern health care ethics and law emphasize personal autonomy as a fundamental value, it does not negate the principle of beneficence and paternalism. However, paternalistic features of health practice have become the exception rather then the rule compared with the traditional medical ethics. Similarly, the balance between personal autonomy and beneficence-based practice is strikingly different, even in different European regions not to mention different parts of the globe. What is important, however, in spite of the differences of interpretation, is that the moral discourse is only alive because of dialogue between these different moral perspectives and principles.

DEVELOPMENT OF INTERNATIONAL RESEARCH GUIDELINES AS A TEST CASE OF THE ARTICLE

Let us also consider the evolution of the international guidelines on biomedical research ethics as another example that might be particularly useful to see the role of the Article in the context of the Universal Declaration on Bioethics and Human Rights. Developments in the field of research ethics clearly demonstrate all the mentioned features and conditions of the international multicultural bioethical discourse that is also supposed to be the central aim pursued by the Declaration. All the international research ethics guidelines (for example, the Declaration of Helsinki, the Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by CIOMS) are based on the plurality of ethical principles which complement each other. Even if

the primacy of the human being and the requirement of informed consent are assigned a priority when deciding about the ethical acceptability of a research project, it is never enough to base the analysis on these principles. The risk/benefit ratio, protection of privacy and vulnerable, just distribution of risks and benefits to research subject population, benefit sharing and other principles of the UNESCO Declaration should be considered by the ethics committee issuing an approval for a particular research project. It might be claimed that the above-mentioned principles compose a convergent system of complementary and interrelated ethical principles constituting an ethical framework of research ethics. Having said that, it is important to note that it is very rare that all the mentioned principles are fully followed and fulfilled. Very often research ethics committees have to find a way to balance the principles. For example, some important areas of research, such as emergency medicine research, research on incapable persons or large-scale epidemiological studies, could not be carried out following the requirement of informed consent. This does not mean, however, that these research projects would be prohibited. Usually they are granted an approval balancing the lack of consent from potential research participants by other ethical principles, such as a favourable risk/benefit ratio and appropriate safeguards to protect the privacy of research participants. Of course, different countries would differ in their attitude to these types of research, usually asking for additional safeguards or by just following the international ones. These differences might be even more expressed in some areas where disagreements reach the most extreme forms, as is the case with embryonic stem cell research. This research is at the moment explicitly prohibited by some countries and allowed in others. In this particular case we might think about the remaining controversy, which demonstrates the inherent discrepancy between some moral views. It seems that international bioethics should be able to 'tolerate' this ultimate incommensurability between different moral views on some controversial issues.

DECLARATION AS A UNIVERSAL BIOETHICS INSTRUMENT

It is important to note that bioethics mainly concentrates on those moral issues which have not yet been resolved by consensus. For example, some of the practices, which might be regarded as clearly immoral, are not ethically problematic in a sense that everybody feels uncomfortable about it and/or disapproves a certain course of action. For example, it would be a platitude to argue that killing the innocent or stealing are bad. Moreover, these kinds of practices are in most social circumstances prohibited by law and presuppose a

clear sanction for breaking the rules. On the other hand, bioethical discussion starts exactly at the point when there is no clear consensus about the case. That is why the Declaration based on a plurality of non-hierarchical principles might serve as a tool to start the bioethical debate, which might result in a consensus of the competing positions. Such a consensus, as has been already pointed out, might be achieved by the possibility of balancing the role of ethical principles in each particular case.

However, the price of seeing bioethical principles as non-hierarchical ones may give rise to uncertainty and contradictions because of the absence of a clear guidance on how to act in front of the contradicting interpretations of a particular bioethical case. This uncertainty might be seen as a weakness of the Declaration in not providing a clear unidirectional guide for action. On the other hand, however, the possibility to have a culture-specific interpretation, and especially a non-directive character, of balancing ethical principles is a fundamental feature of the Declaration that allows it to serve as a universal instrument potentially acceptable, even by very different cultures and societies. This is also the way to provide a general framework of bioethical reasoning.

'PLURALISTIC CASUISTRY'

It might be argued that the Declaration follows on what Brody (1998) has called a methodology of casuistic pluralism as opposed to monistic ethical theories based on a single moral principle or value. He argues that casuistic pluralism much better reflects the practice of ethical decision-making both at policy level and for case analysis. Pluralistic interpretation of bioethical principles does not presuppose an *a priori* hierarchy of principles, and therefore all the principles should be taken into consideration when dealing with a particular bioethical problem. In that sense the Declaration escapes from a moral reductionism, diminishing moral reasoning to one particular ethical value.

CONCLUSION

This article deals with the methodology of ethical reasoning. In addition to the interrelation and complementarity of the principles, we have to be conscious about other related features of the moral discourse implicit in the Declaration. These features are: the pluralistic and non-hierarchical relationship between the principles that might lead to moral conflicts. These conflicts could be solved by finding a balance between competing principles or choosing a culturally sensitive interpretation of the principle. Finally, the mentioned features provide an opportunity for the Declaration to be accepted by different cultures and traditions.

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Chapter 29

ARTICLE 27: **LIMITATIONS ON THE APPLICATION OF THE PRINCIPLES**

Patrick Robinson

Article 27 – Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

WHY IS THIS ARTICLE IN THE DECLARATION?

The main achievement of the Declaration is that it anchors the 15 principles firmly in human rights law. The Declaration is replete with references to human rights as the standard-setter in bioethics, and the instrument itself is entitled the Universal Declaration on Bioethics and Human Rights. In the Preamble there are five references to human rights, including a provision that the Declaration is to be interpreted in a manner consistent with domestic and international law in conformity with human rights law. In the operative paragraphs many provisions (Articles 2(d), 3(1) and (2), 6(2), 7(b), 9, 10, 11, 27 and 28) make the validity of certain decisions dependent on their consistency with human rights law, the dignity of the human person and respect for, and observance of, human rights and fundamental freedoms.

Human rights law has its modern genesis in the 1948 Universal Declaration of Human Rights and the 1966 International Covenant on Civil and Political Rights as well as the 1966 International Covenant on Economic, Social and Cultural Rights (the 'ICCPR' and the 'ICESCR' respectively). A feature of the law is that human rights may only be curtailed for certain societal purposes. Thus Article 29(2) of the Universal Declaration of Human Rights provides that rights:

> …shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order, and the general welfare in a democratic society.

Another typical limitation is Article 8(2) of the European Convention for the Protection of Human Rights and Fundamental Freedoms (hereafter, 'the European Convention on Human Rights'), which provides:

> There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

Most of the rights in the ICCPR are subject to certain limitations and exceptions. A typical limitation is the provision in Article 18(3) that:

> Freedom to manifest one's religion or beliefs may be subject only to such limitations as are prescribed by law and are necessary to protect public safety, order, health, or moral or the fundamental rights and freedom of others.

Similarly, Article 26(1) of the 1997 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 (hereafter, 'the European Convention') provides:

> No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.

It was inevitable, therefore, that, because of the linkage established by the Declaration between the principles and human rights, the Declaration would have a provision setting out the circumstances in which limitations may be placed on the principles. This is necessary because, even though the Declaration is not a legally binding instrument, States are exhorted in Article 22 to take the

necessary measures, whether of a legislative, administrative or other character, to give effect to its principles. It is vital, therefore, that the Declaration indicate clearly to States and its other addressees the instances in which they may impose limitations on the application of the principles.

HISTORY OF THE PROVISION IN THE NEGOTIATIONS

In the Third Outline of the Text of the Declaration on Universal Norms on Bioethics (27 August 2004), Article 29 reads:

> No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by law [and necessary in a democratic society] in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others (IBC, 2004).

This text was based on Article 26 of the European Convention. There are, however, two differences: first, the phrase 'and necessary in a democratic society' is bracketed; and secondly, the Draft of the International Bioethics Committee requires that the law prescribing the limitations be consistent with international human rights law.

A written consultation was carried out between October and December 2004 on the Third Outline. Among the replies was the following text:

> No restrictions ~~shall~~ **should** be placed on the principles set out in this Declaration other than those prescribed by **domestic** law**s and policies**. [~~and necessary in a democratic society~~]. **Such restrictions would be permissible only for important societal interests such as** ~~in the interest of~~ public safety, ~~for the prevention of~~ crime **prevention**, ~~for the~~ protection of public health or ~~for~~ the protection of the rights and freedoms of others (UNESCO, 2005).

In the written consultation the retention of the bracketed phrase 'and necessary in a democratic society' was supported by some countries and opposed by others.

The Draft on Limitations that was prepared by the IBC and considered by the Intergovernmental Meeting of Experts reads:

> No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by law and which are consistent with international human rights law and necessary in a democratic society in the interest of public safety, for the prevention of crime, for

> the protection of public health or for the protection of the rights and freedoms of others (Report expert meeting, 2005a).

However, the IBC Draft was changed at the 2nd Session of the Intergovernmental Meeting of Experts to read:

> If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law (Report expert meetings, 2005b).

It is not apparent why the phrase 'including laws in the interests of …' was introduced, since it renders non-exhaustive the list of purposes in respect of which there may be a limitation – an approach that is unusual in human rights instruments (See, for example, Article 29(2) of the Universal Declaration of Human Rights, Article 8(2) of the European Convention on Human Rights, Article 18 of the ICCPR and Article 26(1) of the European Convention, which all have closed lists of purposes in respect of which limitations may be imposed). This issue is addressed in the next section.

WHAT DOES THE ARTICLE MEAN?

It is useful to examine this Article against the background of the main requirements in human rights law for limitations on human rights; these are that the limitations must be prescribed by law and be a strictly necessary and proportionate means of protecting the specified societal interest[1].

The beginning of the Article, 'if the application of the principles of this Declaration is to be limited' indicates the exceptional nature of the provision permitting limitations on the applications of the principles.

The provision that the limitation 'should be by law' is consistent with the requirement that limitations must be prescribed by law.

However, the Declaration does not follow the traditional approach, as reflected in the IBC Draft, in human rights instruments of establishing a closed list of purposes in respect of which there may be a limitation. The advantage of a closed list is that it promotes certainty and clarity for the addressees of the Declaration in the very important area of limitations on the application of the principles. It is not clear why the open-ended approach, which results from the phrase 'including laws in the interests of …' was followed. However, as drafted, the effect is that, apart from a limitation

being imposed by law for the specific purposes identified (public safety, the prevention of crime, the protection of public health or for the protection of the rights and freedoms of others), States could make laws providing for limitations for other purposes. Although this list is very wide, it is conceivable that other purposes could be identified for limitations.

Since Article 27 reflects all the purposes in the IBC Draft, and that Draft was based on Article 26(1) of the European Convention, it is helpful to ascertain what purposes were deliberately excluded from the scope of that article and why they were excluded. The Explanatory Report on Article 26(1) of the European Convention states that:

> defending the economic well-being of the country, public order or morals and national security are not included amongst the general exceptions referred to in the first paragraph of the Article, unlike Article 8 of the European Convention on Human Rights. It did not appear desirable, in the context of the Convention, to make the exercise of fundamental rights chiefly concerned with the protection of a person's rights in the health sphere subject to the economic well-being of the country, to public order, to morals or to national security (Council of Europe, 1996: para. 156).

The Explanatory Report also mentions that 'war and armed conflict were also ruled out as possible grounds for exceptions. However, this was not meant as preventing the law from taking specific measures in the military aiming at protecting public health in that particular context' (Council of Europe, 1996: para. 158).

Even if one takes into account the regional nature of the European Convention as against the universal scope of the Declaration, the question arises whether that reasoning for excluding those purposes would not be equally applicable to Article 27 of the Declaration. As drafted, however, the open-ended nature of the purposes identified enables a State to legislate for limitations on the application of the principles in respect of any purpose other than those mentioned in the Article, including those specifically omitted from Article 26 of the European Convention, that is, defending the economic well-being of the country, public order or morals, national security, war and armed conflict. Perhaps it was felt that the open-ended and more flexible approach was more appropriate for a non-binding instrument such as the Declaration. It is to be noted that that approach is reflected in the following proposal mentioned earlier (see the paragraph on the history of the provision and the reply to the Third Outline, discussed above): '… Such restrictions would be

permissible only for important societal interests *such as* [my emphasis] public safety, crime prevention…' (UNESCO, 2005).

A possible adverse consequence of the open-ended nature of the purposes in respect of which limitations may be made is that, conceivably, a State could legislate to protect a purpose that does not qualify as the kind of societal interest that is generally protected by human rights law. However, Article 27 requires that the law providing for the limitation must be consistent with international human rights law. Moreover, the *eiusdem generis* rule of interpretation would result in the conclusion that the purpose in respect of which a limitation may be made must be similar to the kind of societal purposes set out in Article 27.

Another difference from the IBC text is that Article 27 does not explicitly state that the limitation must be necessary to achieve the declared purpose. Human rights law requires that limitations on human rights be strictly necessary for and proportionate to the societal interests to be protected. However, in light of the centrality of human rights law to the Declaration as a whole, including the Preamble, notwithstanding this omission, there would be no difficulty in interpreting the Article as a call for this requirement. Moreover, the Article does require that the law providing for the limitation be consistent with international human rights law.

Also noteworthy is that the article omits the phrase 'necessary in a democratic society' that was included in the IBC text. Again, the requirement that any law limiting a principle of the Declaration must be consistent with international human rights law is applicable. The jurisprudence of the international and regional human rights bodies shows that any assessment of whether a limitation on a right is lawful must address whether the limitation is 'necessary in a democratic society'. It follows, therefore, that to be consistent with international human rights law, any limitation on a principle must be 'necessary in a democratic society'. If the limitation is found not to be so, the law providing for that limitation would thus be inconsistent with international human rights law.

The requirement that the law limiting the principle be consistent with international human rights law means that that latter law ultimately becomes the determinant of the legitimacy of the law limiting the principle.

This, then, is the meaning of the article: States should only impose limitations on the application of the principles in exceptional circumstances; if they do, it must be done by a law prescribing limitations necessary for the protection of certain societal interests, including public safety, the prevention of crime, the protection of public health, and the protection of the rights and freedoms of others. That law must, in any event, be consistent with

international human rights law. All the requirements of international human rights law, including those not expressly mentioned, such as that the limitation must be one that is necessary in a democratic society to achieve the stated purpose, must be met by the prescribing law. This applies equally to a law prescribing a limitation on the application of the principles for a purpose not expressly set out in the Article.

HOW CAN THE ARTICLE BE APPLIED?

Examples of the application of the article would be laws providing for:

- the use of DNA tests to identify persons in connection with a criminal investigation – for the investigation, detection and prosecution of criminal offences;
- a court to make an order for a test to be carried out to determine parentage – for the protection of the rights of others;
- isolation of patients with infectious diseases – for the protection of public health;
- coercive measures in respect of a mentally ill-person – to protect the rights and freedoms of others;

Endnote 1

See General Comment No. 27, UN Doc. CCPR/C/21/Rev.1/Add.9 (1999) para. 16 – The application of restrictions in any individual case must be based on clear legal grounds and meet the test of necessity and the requirements of proportionality'; also *Dudgeon vs. the UK*, European Court of Human Rights, Application No. 7525/76 Judgement of 22 October 1981 – Paras. 42–61 and *Chassagnou and others vs. France*; European Court of Human Rights, Applications Nos. 25088/94, 28331/95 and 28443/95, Judgement of 29 April 1999, Paras. 104–117; *Slobodan Milošević vs. Prosecutor*, Case No. IT-02-54-AR73.7, Decision on Interlocutory Appeal of the Trial Chamber's Decision on the Assignment of Defence Counsel, 1 November 2004, para. 17.

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Chapter 30

ARTICLE 28: **DENIAL OF ACTS CONTRARY TO HUMAN RIGHTS, FUNDAMENTAL FREEDOMS AND HUMAN DIGNITY**

Patrick Robinson

Article 28 – Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.

WHY IS THIS ARTICLE IN THE DECLARATION?

Substantially similar provisions are to be found in many human rights instruments, including the Universal Declaration of Human Rights, the European Convention on Human Rights, and the International Covenant on Civil and Political Rights (ICCPR).

Article 30 of the Universal Declaration of Human Rights provides that:

> Nothing in this Declaration may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms set forth herein.

Article 17 of the European Convention on Human Rights provides that:

> Nothing in this Convention may be interpreted as implying for any State, group or person any right to engage in any activity or perform any act aimed at the destruction of any of the rights and freedoms set forth herein or at their limitation to a greater extent than is provided for in the Convention.

Article 5 (1) of the International Covenant on Civil and Political Rights provides that:

> Nothing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or perform any act aimed at the destruction of any of the rights and freedoms recognized herein or at their limitation to a greater extent than is provided for in the present Covenant.

HISTORY OF THE ARTICLE

The First Outline of the Declaration had the following line: 'Denial of acts contrary to human rights, fundamental freedoms and human dignity' (as finalized on 15 June 2004; IBC, 2004a).

In the Second Outline of a Text of the Declaration, elaborated by the Drafting Group for consideration by the IBC, there was the following provision:

> Denial of acts contrary to human rights, fundamental freedoms and human dignity.
>
> Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity, including, in particular, the principles set out in this Declaration (IBC, 2004b).

This formulation was maintained in the Third Outline (IBC, 2004c). However, it was changed in the Fourth Outline (IBC, 2004d) by omitting the phrase 'including, in particular, the principles set out in this Declaration'; and ultimately this was the final text adopted by the IBC (IBC, 2005).

The 2nd Session of the Intergovernmental Meeting of Experts approved the formulation of the Preliminary Draft Declaration as approved by IBC in February 2005, without the phrase referring to the principles set out in the Declaration (Report expert meeting, 2005).

WHAT DOES THE ARTICLE MEAN?

In order to ascertain the meaning of the article, the purpose of the corresponding provision in human rights instruments must be examined.

The provision was introduced in the Universal Declaration of Human Rights in the wake of the atrocities of the Second World War, and its purpose was to prevent reliance on the rights set out therein by any State, group or person in order to justify infringement of the rights and freedoms of others.

The provision was designed to prevent groups with Nazi, fascist or other totalitarian ideologies from invoking provisions in the Declaration, such as those for the right of association and freedom of speech, to justify their activities (Bossuyt, 1987)[1].

Article 28 differs in its formulation and, perhaps, also in substance, from the traditional language in human rights instruments. The concern of those instruments is to ensure that rights set out therein are not destroyed or limited by misinterpretation and misuse of any of their provisions. However, the concern of Article 28, at least in its final version, is not to protect rights or interests *set out in the Declaration*, but human rights, fundamental freedoms and human dignity in general.

The earlier version of the Article produced in the Second Outline (IBC, 2004a) also had the present formulation, but with the phrase 'including, in particular, the principles set out in this Declaration' after the reference to 'human rights, fundamental freedoms and human dignity'. That formulation would have been more consistent with the traditional approach; many will question why the Declaration is concerned with the protection of human rights in general, as distinct from the principles which it establishes.

The purpose of Article 28 is to prevent any misinterpretation and misuse of any of its provisions to justify any activity that contravenes human rights, fundamental freedoms and human dignity. Of course, to the extent that any of the principles has the status of a human right or fundamental freedom, it would be protected by the Article. However, even though principles such as informed consent, privacy and confidentiality, and non-discrimination are derived from fundamental human rights and by reason of the support they have in State practice arguably reflect customary international law, or are close to achieving that status, it is doubtful whether that claim could be confidently made in respect of the others.

However, those principles that do not have the status of a human right or fundamental freedom may nonetheless be protected on the basis that the activity in question is contrary to human dignity. An activity contrary to human dignity would undoubtedly be repugnant to many of the principles of the Declaration, which in many of the provisions such as the Preamble, the aims in Article 2 and the crucially important Article 3, call not only for respect for human rights and fundamental freedoms, but also for respect for human dignity.

Endnote 1

In the *Glimmerveen Hagenbeek* Case, Glimmerveen complained to the European Commission on Human Rights about his criminal conviction for

possessing, with the aim of distribution, leaflets of the 'Nederlandse Volks Unie', a political party, which were found to incite racial discrimination; both applicants also complained that the relevant electoral institutions in the Netherlands had taken action to render invalid the list of candidates of their party. Although the Commission recognized that the complaints implicated the right to freedom of expression under Article 10 of the European Convention on Human Rights and Article 2 of Protocol No. 1 of the Convention, it concluded that, by virtue of Article 17 of the Convention, the applicants could not invoke Article 10 since, *inter alia*, that Article was being invoked to (destroy) (prejudice) the right of others to freedom from discrimination under Article 14. Appls. 8348 and 8406/78, D&R 18 (1980) 187 (194-197).

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CONCLUDING WORDS

Pierre Sané

THE PFIZER OR TROVAN TRIAL CASE

The city of Kano, the second largest city in Nigeria, was struck in early 1996 by an epidemic of meningitis. In poor and overpopulated areas, the disease claimed many victims. More than 15,000 children died and thousands were permanently disabled.

The government, assisted by Médecins Sans Frontières, provided free emergency treatment in the Infectious Diseases Hospital in Kano. The pharmaceutical company Pfizer, the largest in the world, offered its help by making available a new antibiotic drug Trovafloxacin, known under its brand name Trovan. Pfizer stated that it was a humanitarian gesture to help the government cope with the epidemic. The advantage of the medication is that it can be taken orally; it is therefore less burdensome for children than the standard treatment by injection. Trovan, however, had never been tested in a disease outbreak and never been administered to children orally. Six weeks after it first learned of the epidemic, a team of Pfizer researchers joined the physicians in the Kano government hospital and started to recruit children into a clinical trial. At least 200 children were included, with a control group receiving low doses of ceftriaxone, an approved and effective antibiotic to treat bacterial meningitis. Two weeks later, once the trial had been completed, the Pfizer researchers left Kano, although the epidemic continued.

In December 1996, Ffizer made an application with the Food and Drug Administration (FDA) for approval to market Trovan for various uses, including treatment of infectious diseases in children. The FDA criticized the Kano studies and announced that the application concerning meningitis would be declined, subsequent to which Pfizer withdrew the application. In 1998, Trovan was authorized by the FDA for treatment of several adult illnesses. However, reports were soon received about liver damage and the use of the drug was severely restricted. The sale of Trovan has never been authorized in Europe.

A governmental committee of medical experts investigated the Trovan trial and concluded that it was illegal and unethical. The desperation of the parents and the emergency situation made it easy to enrol patients in the trial, suggesting free treatment for a serious disease. Parents with infected children were often not aware that they were included in a clinical trial; they were afraid for their children and did not ask many questions. They received a pink paper with Pfizer's name and the treatment dates. In many cases no permission was requested to test the drug. Pfizer argued that informed consent could not be obtained from parents because they were illiterate. In this impoverished part of the country, few parents indeed could speak or write English. They certainly did not understand that the drug was experimental, that they had the right to refuse or withdraw participation, or that standard treatment was available in the same hospital free of charge.

However, the report of the Nigerian medical experts, completed in 2001, was never released. In May 2006, the *Washington Post* (informed by a whistleblower) brought a copy of the confidential report into the open, and reported on its front page that Pfizer had conducted an illegal trial of an unregistered drug. The publication created an international outrage. Public opinion regarded the experiment as a clear case of exploitation of the ignorant, in violation of international regulations, using poor, illiterate and uninformed people as guinea pigs.

After the publication of the information, the Nigerian Minister of Health appointed a panel of medical experts. They examined the trial, collected documents and interviewed people. The local physician, who had been, according to Pfizer, directing the experiment, had been principal director only in name; he stated that he had not even seen some of the publications of which he was the lead author. It also appeared that the trial was not approved by an ethics committee, although Pfizer produced a letter of approval dated March 1996. At that time no ethics committee at Kano hospital or at national level existed.

In the meantime, the case has resulted in several lawsuits in the US as well as in Nigeria. In 2002, a group of Nigerian families sued Pfizer in the Federal District Court of New York because the trial with the untested new drug had caused grave injuries and had not followed informed consent procedures. Prior animal testing had indicated that Trovan might have significant side effects in children, such as liver damage. It was argued that the treatment with ceftriaxone in the control group was inadequate, using only one third of the recommended dosage. Furthermore, follow-up evaluations after the trial were absent as the team never returned to Kano. The lawsuit was

dismissed since the events in Nigeria were, according to the Court, outside the jurisdiction of the US Courts.

In May 2006, the authorities in Kano filed civil and criminal charges against Pfizer. The federal government of Nigeria did the same in 2007, seeking US$7 billion in damages, arguing that the company never obtained approval from the relevant regulatory agencies. The government also argued that the illegal conduct of Pfizer had been responsible for the rejection of polio vaccination by citizens in Kano State during 2005 and 2006. The polio vaccination campaigns had been boycotted out of fear, with Muslim leaders arguing that it was a Western plot. Parents refused to have their children immunized against polio, the state governor suspended the programme, and vaccine samples were sent abroad for testing. The vaccine he finally ordered was produced in Indonesia.

In January 2008 the Federal High Court in Abuja ordered the arrest of current and former Pfizer staff in the country. However the court battle has continued. The latest news is that the parties involved are trying to reach an out-of-court settlement.

THE NEED FOR BIOETHICS INFRASTRUCTURES

The above Pfizer case, or in more neutral terms, the Trovan trial case, is raising a number of questions in the field of bioethics. But first of all, the case illustrates the need for international guidance. Cases like this show perfectly why the Member States of UNESCO, in particular from the developing world, have asked the Organization to develop normative instruments such as the Universal Declaration on Bioethics and Human Rights. Over the last few decades, many countries in the developing world have established a bioethical infrastructure with ethics committees, legislation and ethics education in order to ascertain that clinical trials will be executed according to bioethical principles such as informed consent, appropriate balancing of harms and benefits, and justice. But with the increasing internationalization of medical research, there is a tendency to carry out clinical trials that are difficult to implement in certain countries, and where the co-operation of research subjects is difficult to obtain, in other countries where such infrastructures do not exist.

One of the problems illustrated in the above case is that this globalization of research is not associated with a similar globalization of bioethics. Following the abuses during the Second World War and many scandals in Western countries (such as the Tuskegee case in the United States), the ethical principle of informed consent, for example, has been firmly rooted in all regulation and

legislation concerning research with human beings. It is unacceptable that experimentation with a new drug in a country like Nigeria should not apply this principle. The company even argued that it could not be applied because the research subjects were illiterate. This is an unjust argument because providing and understanding information, and subsequently consenting to participate, does not depend on the ability to read and write. It is also a curious justification. Researchers know well that in chaotic circumstances such as epidemics and where there are seriously ill children, the proper conditions for informed consent often do not exist, such that the researchers will have to make greater efforts to obtain consent. The Trovan case is particularly complex since research involving persons without the capacity to give consent, and in particular children, is controversial in bioethics. During the negotiations among Member States of UNESCO over the final draft of the Universal Declaration on Bioethics and Human Rights, the formulation of Article 7 concerning this special topic was lengthy and difficult. The text of the Article states clearly that research should only be carried out when there is a direct health benefit for the subject and if there is no research alternative of comparable effectiveness. In the Trovan case the direct health benefit for the children was unclear and the claimed advantage (oral ingestion) was dubious since meningitis is often associated with nausea. There was effective alternative medicine available, but the parents were not told that elsewhere in the same hospital Médecins sans Frontières was providing free standard treatment, while at the same time half of the children included in the Pfizer trial received another standard drug but with a lower than recommended dosage. It is clear that the conduct of the trial in Kano would never have been accepted in a similar hospital in Amsterdam, for example.

The case therefore demonstrates two important changes in the field of bioethics. One is the need to emphasize that ethical principles guiding medical research and health care practices should be truly universal. UNESCO has contributed to this change by adopting three normative instruments in bioethics. Second is the need to make sure these ethical principles are applied in practices all around the world. Adopting declarations is one thing; what is really necessary is to apply the principles in research projects and care practices in all Member States.

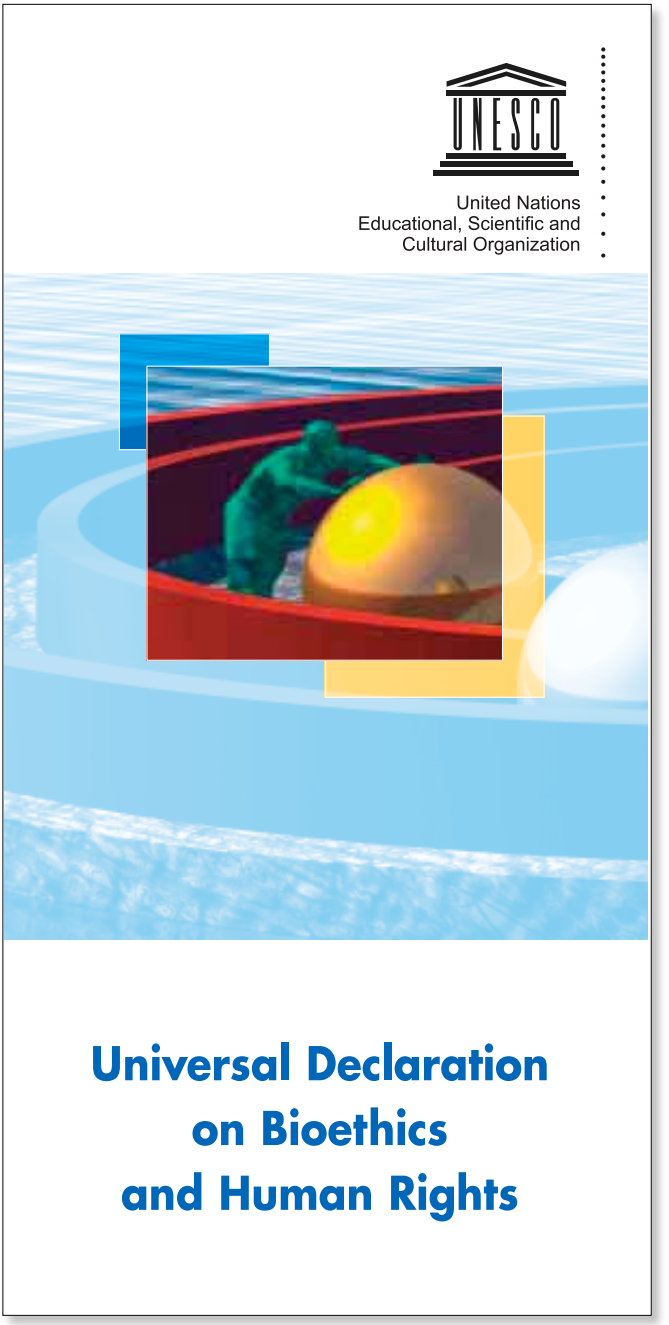
BUILDING CAPACITIES IN BIOETHICS

The major challenge for international organizations such as UNESCO nowadays is to 'translate' the consensus on bioethical principles, expressed in the Universal Declaration on Bioethics and Human Rights, into concrete and effective practices. In previous chapters in this volume it is shown how

this 'translation' can be effectuated. It was possible for the Trovan case to occur because of the absence of functional ethics committees and the lack of legislation and oversight. It is therefore essential that all Member States build up their own expertise and capacity to review research and to advise the government on legislation and regulation. UNESCO assists the Member States in establishing National Bioethics Committees, as is also requested in the Declaration. When such committees exist, policy-makers will have the assistance of bodies of experts who can make recommendations concerning difficult issues in the field of bioethics, and who can develop and analyze draft legislation. National Bioethics Committees, as independent advisory bodies on policy, also have an important role to play in promoting public debate and making citizens aware of their moral rights and duties in the practice of health care and as potential subjects of research. Finally, these committees will contribute to the introduction and development of the teaching of ethics. Educating new generations of scientists and health professionals sensitive to the ethical issues emerging from scientific knowledge and its applications is in the longer run an excellent way to make scientists and professionals familiar with the global standards in bioethics.

It is clear that with a more sensitized and informed population, ethically educated physicians and researchers, functioning ethics committees and legislation concerning medical research, the Trovan case would have been more unlikely. However, until the inequity in bioethics infrastructures at a global level is eliminated, developing countries will continue to run the risk of being the test laboratories for hazardous experiments and controversial trials.

UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS



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Foreword

In October 2005, the General Conference of UNESCO adopted by acclamation the Universal Declaration on Bioethics and Human Rights. For the first time in the history of bioethics, Member States committed themselves and the international community to respect and apply the fundamental principles of bioethics set forth within a single text.

In dealing with ethical issues raised by medicine, life sciences and associated technologies as applied to human beings, the Declaration, as reflected in its title, anchors the principles it endorses in the rules that govern respect for human dignity, human rights and fundamental freedoms. By enshrining bioethics in international human rights and by ensuring respect for the life of human beings, the Declaration recognizes the interrelation between ethics and human rights in the specific field of bioethics.

Together with the Declaration, the General Conference of UNESCO adopted a resolution which calls upon Member States to make every effort to give effect to the principles set out in the Declaration and invites me to take appropriate steps to ensure the follow-up to the Declaration, including its widest possible dissemination.

This brochure constitutes a first tool for the dissemination of the Declaration and is aimed at contributing significantly to knowledge of the Declaration worldwide and to understanding of the principles set out therein, so that human beings everywhere can benefit from the advances of science and technology within the framework of respect for human rights and fundamental freedoms.

Koïchiro Matsuura

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Universal Declaration on Bioethics and Human Rights*

The General Conference,

Conscious of the unique capacity of human beings to reflect upon their own existence and on their environment, to perceive injustice, to avoid danger, to assume responsibility, to seek cooperation and to exhibit the moral sense that gives expression to ethical principles,

Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,

Recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Resolving that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for humankind and for the environment,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of UNESCO on 11 November 1997 and the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003,

Noting the United Nations International Covenant on Economic, Social and Cultural Rights and the International Covenant on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the General Assembly of the United Nations in 1993, the UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989, the International Treaty on Plant Genetic Resources for Food and Agriculture which was adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

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annexed to the Marrakech Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001 and other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO),

Also noting international and regional instruments in the field of bioethics, including the 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 of the Council of Europe, which was adopted in 1997 and entered into force in 1999, together with its Additional Protocols, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1983, 1989, 1996 and 2000 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences, adopted in 1982 and amended in 1993 and 2002,

Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law,

Recalling the Constitution of UNESCO adopted on 16 November 1945,

Considering UNESCO's role in identifying universal principles based on shared ethical values to guide scientific and technological development and social transformation in order to identify emerging challenges in science and technology taking into account the responsibility of the present generations towards future generations, and that questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data and taking account not only of the current scientific context but also of future developments,

Aware that human beings are an integral part of the biosphere, with an important role in protecting one another and other forms of life, in particular animals,

Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and *emphasizing* that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Recognizing that health does not depend solely on scientific and technological research developments but also on psychosocial and cultural factors,

Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole,

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Bearing in mind that cultural diversity, as a source of exchange, innovation and creativity, is necessary to humankind and, in this sense, is the common heritage of humanity, but *emphasizing* that it may not be invoked at the expense of human rights and fundamental freedoms,

Also bearing in mind that a person's identity includes biological, psychological, social, cultural and spiritual dimensions,

Recognizing that unethical scientific and technological conduct has had a particular impact on indigenous and local communities,

Convinced that moral sensitivity and ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments,

Considering the desirability of developing new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the interest of humanity,

Recognizing that an important way to evaluate social realities and achieve equity is to pay attention to the position of women,

Stressing the need to reinforce international cooperation in the field of bioethics, taking into account, in particular, the special needs of developing countries, indigenous communities and vulnerable populations,

Considering that all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research,

Proclaims the principles that follow and *adopts* the present Declaration.

* Adopted by acclamation on 19 October 2005
by the 33 rd session of the General Conference of UNESCO

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General provisions

Article 1 Scope

1. This Declaration 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.

2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

Article 2 Aims

The aims of this Declaration are:

(a) 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;

(b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;

(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;

(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;

(e) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;

(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;

(g) to safeguard and promote the interests of the present and future generations;

(h) to underline the importance of biodiversity and its conservation as a common concern of humankind.

Principles

Within the scope of this Declaration,
in decisions or practices taken or carried out by those to whom
it is addressed, the following principles are to be respected.

Article 3 Human dignity and human rights

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

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

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Article 4 Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, 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

1. 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.

2. 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 modalities for withdrawal of consent. 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.

3. 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

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

2. 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:

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

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Article 15 Sharing of benefits

1. 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:

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

(b) access to quality health care;

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

(d) support for health services;

(e) access to scientific and technological knowledge;

(f) capacity-building facilities for research purposes;

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

2. 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 respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

Application of the principles

Article 18 Decision-making and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 19 Ethics committees

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) provide advice on ethical problems in clinical settings;

(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20 Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21 Transnational practices

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.

2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.

3. Transnational health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.

4. When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation.

5. States should take appropriate measures, both at the national and international levels, to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials.

Promotion of the Declaration

Article 22 Role of States

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.

2. States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, as set out in Article 19.

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Article 23 Bioethics education,training and information

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.

2. States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 24 International cooperation

1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.

2. Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

3. States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 25 Follow-up action by UNESCO

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).

2. UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

Final provisions

Article 26 Interrelation and complementarity of the principles

This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

Article 27 Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

Article 28 Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.

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United Nations Educational, Scientific and Cultural Organization
Division of Ethics of Science and Technology
Social and Human Science Sector
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www.unesco.org/shs/ethics
SHS/EST/BIO/06/1

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In October 2005, UNESCO Member States adopted by acclamation the Universal Declaration on Bioethics and Human Rights. For the first time in the history of bioethics, some 190 countries committed themselves and the international community to respect and apply fundamental ethical principles related to medicine, the life sciences and associated technologies.

This publication provides a new impetus to the dissemination of the Declaration, and is part of the Organization's continuous effort to contribute to the understanding of its principles worldwide. The authors, who were almost all involved in the elaboration of the text of the Declaration, were asked to respond on each article: Why was it included? What does it mean? How can it be applied?

Their responses shed light on the historical background of the text and its evolution throughout the drafting process. They also provide a reflection on its relevance to previous declarations and bioethical literature, and its potential interpretation and application in challenging and complex bioethical debates.

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