

UNESCO
INTERNATIONAL BIOETHICS COMMITTEE
INTER-GOVERNMENTAL BIOETHICS COMMITTEE
PARIS, 24 JANUARY 2005

THE UNESCO BIOETHICS DECLARATION - 12 POINTS*

Justice Michael Kirby**

PROCEDURAL INNOVATIONS

The preparation of the proposed UNESCO Declaration on Bioethics has witnessed important innovations in the methodology of the International Bioethics Committee of UNESCO (IBC). These innovations are worth recalling because they have significance for the final product of the process. They also mark a new stage in the advance in the transparency of the procedures of the IBC. They are, in some ways, a model for the activities of the Organisation as a whole.

* Text for an address at the opening session of the Inter-Governmental Bioethics Committee held at UNESCO Headquarters, Paris, 24 January 2005.

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Because the IBC was charged by the Director-General in 2004 with the preparation of the proposed Declaration, for presentation to the General Conference of UNESCO in October 2005, it became necessary to move with considerable speed and efficiency to complete the task of preparing the final Draft in time. The Draft prepared by the IBC must, when communicated to the Director-General, be subjected to a further and intensive process of consultation within UNESCO, with the Member States, with governmental experts, at regional and national conferences and at meetings with non-governmental organisations, academic institutions, national bioethics bodies and the like. Because the IBC had entrusted the preparation of the Draft Declaration to a Drafting Group, which I have had the honour to chair, it became necessary to institute a series of meetings in 2004, culminating with this meeting in January 2005, during which the draft has evolved.

The IBC engaged in formal consultation with the Inter-Governmental Committee on Bioethics (IGBC) on two relevant occasions, one of which is taking place in January 2005. The Secretariat, from the outset, had consulted widely with Member States, interested bodies and individuals to map the contours of contemporary bioethics; to secure indications of the priorities that deserved attention in this connection; to procure ideas for the shape and content of the proposed Draft Declaration; and to ascertain reactions to the preliminary documentation, out of which

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this project has evolved. I pay tribute to Professors Berlinguer (Member of the IBC, Italy) and DeCastro (Member of the IBC, Philippines). Their initiating paper was the inspiration that has helped to maintain the momentum through the intensive procedures of 2005.

Ultimately, any proposed Declaration, if it is to be accepted, must be prepared in close consultation with the Member States of UNESCO. They will have the last say at the General Conference. The adoption of such an instrument is not only a scientific and specialised endeavour. It also has the inevitable political ramifications that cannot be ignored in the drafting of such an international instrument. This is why, during the meetings of January 2005, consultations will take place not only within the IBC and between members of the IBC who are, and are not, Members of the Drafting Group but also in and with the IGBC and in the innovative Joint Session of the IBC and the IGBC for which the statutes of UNESCO provide.

The object of this Joint Session is to ensure mutual understanding between the scientific experts and governmental representatives; mutual awareness of the sensitivities that cause concern; awareness on the part of the governmental representatives of the considerations of the IBC and of the structure and content of its document; and hopefully the reduction of areas of disagreement, so far as this can be procured.

In the end, the IBC and the IGBC will each perform their own respective functions. The IBC comprises independent experts chosen for their knowledge and skills in relevant disciplines. They must reach their conclusions independently, through processes of consensus. They do not bend in the wind of politics. On the other hand, if their product is to be useful and accepted, it must take into account, and be alert to, relevant concerns expressed on behalf of Member States. Through mutual dialogue and exchanges of this kind, it is hoped that a general consensus will emerge that will sustain the movement towards adoption of the proposed Declaration.

In a most intensive consultation with Member States, the IBC in late 2004, procured a very large number of comments on the then (third) Outline of the Text, prepared by the Drafting Group and accepted for that purpose by the IBC. The large number of responses to this consultation has been compiled in a document, which summarises the proposed amendments by reference to the then articles. The Drafting Group of the IBC proceeded to consider all of the proposed amendments. As each Article was examined, the President of the IBC (Mme Michèle Jean, Canada) and I drew to notice the several proposals concerning suggested amendments, additions, deletions and rewording. It could not be expected that every proposal will be adopted. Many of them overlap with each

other. Many cancel each other out. Nevertheless, all of them have been faithfully considered.

I must pay a tribute to the Secretariat of the IBC under Professor Henk ten Have. It has been committed throughout this process to an open procedure and the transparent widespread publication of the emerging text and associated documents. These have been posted on the IBC website at UNESCO. Anybody interested has been able to follow in detail the development draft and to see the ways in which its provisions were elaborated, the blank spaces were filled, and changes were adopted reflecting the procedure of consultation.

In my experience, this is the most open process for the development of an international instrument, in which I have been engaged. Much credit must also be paid to Ms Sabina Colombo and the staff of the IBC Secretariat. I would single out Dr Judit Sàndor, Chief of the Bioethics Section, for her work on the Explanatory Memorandum. This has been evolving and will provide a useful explanatory text. It too will be posted on the internet, in keeping with the commitment of the IBC to transparency.

The advantage of the foregoing process lies not only in the commentaries and suggestions that it procures. It also helps in the avoidance of errors and misunderstandings. Moreover, it promotes

growing acceptance of the draft and encourages the likelihood that the eventual draft will commend itself to the General Conference of UNESCO, following the political consultations that ensue.

TWELVE ACHIEVEMENTS

1. *Completion on time:* The first achievement of the Draft is that the IBC will complete it on time. This is a remarkable achievement, given that the entire process of elaboration of the Draft has taken less than a year. Given the scale, controversy and novelty of its content, this is, I believe, an extraordinary feat.

If one examines the Fourth Outline of the text¹, which is placed before the January 2005 consultations, and compares it to the earlier outlines, the progress made will be manifest. I confess that, at the stage of the first, second and even third drafts, I sometimes despaired that the timetable set by the Director-General could be maintained. I pay tribute to the President of the IBC (Mme Jean) and the Members of the IBC and especially of the Drafting Group, for the conscientious and disciplined work that they have performed within the time-frame established.

¹ SHS/EST/04/CIB-2/4 Rev 3.

Of course, further time would always be welcomed by experts in performing such a task. Nevertheless, it is true that the adoption of a consensus around the basic principles that inform bioethical decisions, objectively has an element of urgency, given the rapid developments of contemporary science and technology. Moreover, the quest for the perfect is often the enemy of the achievement of the good. Failure to provide a Draft, as requested by the Director-General and contemplated by the General Conference of UNESCO, was not an option open. The IBC was obliged to produce a document. In my view, it is prepared to a high standard and it makes many innovative contributions to the general principles of bioethics and hence, to their attainment and maintenance throughout the world.

2. *Inspirational realisation:* Attending primary school in Australia in 1949, like all other schoolchildren, I received a small pamphlet version of the *Universal Declaration on Human Rights* prepared by the Committee headed by Eleanor Roosevelt and inspired by Rene Cassin and John Humphrey. Reading that instrument, with its inspiring language, influenced me then. Its notions have remained with me ever since.

An early criticism of the proposed Draft Declaration was the failure to include similar inspirational words to enliven contemporary schoolchildren and other citizens to the challenges to humanity presented by the advances in science and technology. In

seeking to meet this criticism, the Draft Declaration now contains opening preambular words that endeavour to place the document into the context of the particular capacity of human beings to reflect on their existence and their environment, to perceive injustice, to avoid danger, to assume responsibility and otherwise to give expression to ethical principles.

The concepts of bioethics are more unclear than those of the Universal Declaration of 1948. World organisations are now more complex. The technology is more puzzling and varied today. Nevertheless, both in the Preamble and in the content of the Draft Declaration, the IBC has sought to express inspiring ideas defensive of human dignity, human rights and fundamental freedoms; assertive of the special responsibility that belongs to humanity; responsive to the need to share benefits and accepting of the obligation of humanity to demonstrate responsibility towards the biosphere.

The central ideas of the Draft Declaration are, or should be, inspiring, for at stake is nothing less than the future of humanity and of all other living things in the biosphere.

3. Rigorous drafting: An important achievement is the commitment of the IBC to an instrument that would display, for the statement and implementation of its principles, rigorous drafting and the adoption of concrete rather than purely obtuse notions. It

is not uncommon in the preparation of international instruments, particularly declarations that are not legally binding as such, for such principles to be stated in extremely broad and vague language couched in the passive voice. It would have been possible for the Drafting Group, and the IBC, to have adopted this style and to have accepted such general statements as "the inherent dignity of the human person, human rights and fundamental freedoms should be fully respected". Suggestions that this might be the approach have been made by several Member States. However, the IBC has instead taken the course of expressing the essential principles and procedural tools by reference to the making of bioethical decisions and the carrying out of bioethical practices.

The great value of this approach is that it addresses the relevant decision-maker at the critical moment of making a decision or carrying out a practice with bioethical implications. It is at that moment that the principles attach. This give the Declaration a much more concrete force. It speaks directly to the persons affected at all relevant levels when such "decisions" and "practices" are being considered. Whilst the alternative drafting would have been possible, it had the disadvantage of abstruseness which the current Draft avoids.

This is not an accidental, but a deliberate, approach on the part of the IBC. It represents a tighter mode of expression and the identification of more particular targets for the principles that are

stated. Several Member States have applauded this approach. Its implementation is greatly improved by contributions from within the IBC and by Member States for the re-statement of the Article dealing with the Scope of the Declaration. It is that Article which explains how the relevant "decisions" and "practices" are to be identified and how, "as appropriate and relevant", the applicable actors are to be identified, who will be bound by the principles to act as so stated.

A disadvantage of a generalised statement of principles in the passive voice, and without the identifiers adopted by the IBC, is that such language leaves much more uncertain the identity of the actor and the moment for relevant action. The Draft Declaration necessarily addresses a wide range of decision-makers and actors - including individuals, professional groups, public or private institutions, corporations or States. Nevertheless, the identification of the Scope of the operation of the Declaration will, sufficiently for its purpose, identify the persons or bodies that must conform to the principles. Such persons and bodies are not merely told to so conform in general terms. They are told, with greater clarity, that they must do so in making "decisions", as defined, and carrying on a "practice", as defined, "involving bioethical issues", as defined.

4. *Inter-relation and complementarity:* Some concern has been expressed that there are inconsistencies between the various principles stated in the Declaration. But this is not only to be

expected; it is inevitable. Inconsistency in bioethical principles is inescapable. Resolving such inconsistency, by balancing the Principles and procuring the best operation of them all, is what bioethics requires. Readers of the Draft Declaration should not be surprised that it necessitates resolution of conflicts between the several principles. That is exactly what must be expected and provided for.

In the Article on Inter-relation and Complementarity of the Principles, this interaction of the Principles is stated in terms conventional to international instruments. However, in order to make this interaction of principles clearer, that Article may be clarified to make plain that where there is a conflict, it should be resolved by balancing all of those Principles that are appropriate and relevant in the circumstances.

In bioethical decision-making, as often in the law and other disciplines, it is not unusual to have to draw lines and to distinguish a case where the principles apply from one in which they do not. This necessity is fully recognised in the Draft Declaration.

5. Foundation in human rights: A most important achievement of the Draft Declaration is that it anchors the principles which it espouses, firmly in the rules governing human dignity, human rights and fundamental freedoms.

Hitherto, bioethics has substantially developed along two broad streams. One of them, from ancient times, derives from the rules developed in the profession of medicine, for the conduct of medical treatment. Another, in more recent times, has drawn upon the developing international law of human rights. One of the important achievements of the Draft Declaration is that it seeks to marry these two streams. It aims to establish clearly the conformity of bioethics with international human rights law. Because UNESCO is an agency of the United Nations, such an expression of the principles of bioethics will cause no surprise.

The United Nations has been instrumental in the development of the fundamental principles of human rights. At recent international gatherings of bioethicists, the importance of reconciling and inter-relating the hitherto divergent streams of bioethics has been emphasised. The Draft Declaration lists conformity with human dignity, human rights and fundamental freedoms as the first of the principles that it sets forth. It is to be hoped that this will encourage and promote greater awareness amongst people and bodies making bioethical decisions and carrying out such practices as well as bioethicists of the relevant developments of international human rights law.

6. *Social responsibility principle:* Another important and innovative principle of the Draft Declaration grows out of recent debates of the IBC and at meetings of bioethicists, sociologists,

philosophers and other experts. It also emerges from the discussions within the IBC and IGBC, stimulated by the representations of many Member States, organisations and individuals.

The expression of the social responsibility principle is designed to address the attention of bioethicists to the practical concerns of bioethics, as viewed in most States and by most people of the world. Except in relatively few developed countries, the real urgencies of contemporary bioethics include access to healthcare, to adequate nutrition and drinkable water, to the reduction of poverty and illiteracy, the improvement of living conditions and the elimination of unjust marginalisation of individuals and groups. Because this is the real world in which bioethical issues must, in most countries, be resolved, it is necessary to include reference to these concerns and to the duty of all those who make decisions and carry on practices relevant to bioethical issues, where relevant, to address and be conscious of such urgent and practical considerations.

Many Member States and some members of the IBC urged upon the IBC the inclusion in the Draft Declaration of specific articles relevant to such basic concerns as access to quality healthcare and essential medicines. Whilst such provisions have not been included in the final draft, the IBC has not overlooked the importance and urgency of these considerations. Instead, some of

the chief of them, in a non-exhaustive list, have been included in the innovative Social Responsibility Principle that is designed to signal acceptance of the wider dimension in which bioethical issues now arise to be resolved.

7. Structure of the principles: Earlier drafts of the Declaration contained provisions, or sections still to be elaborated, concerning differentiation between so-called "fundamental principles" and "derived principles" or "general principles" and "specific bioethical issues".

There is much support in the literature on bioethics for the distinction between particular principles and the assertion that some were either "fundamental" or "derived". The difficulty of drawing this distinction was ultimately accepted by the IBC and hence the Principles are collected without this differentiation. Indeed, there is no hierarchy of the principles, as such. Nevertheless, they are stated in a deliberate order which the IBC considers to be both logical and appropriate.

Similarly, the section of the earlier texts², providing for the inclusion of specific articles concerning some of the identified issues of contemporary bioethics, given priority by Member States

² See eg Third Outline of a Text, Elaboration of the Declaration on Universal Norms on Bioethics: SHS/EST/04/EIB-2/4 Rev 2.

in answer to the Secretariat consultation, has been deleted. In part, this was because of the recognition by the IBC that many, most, if not all of such specific issues were highly controversial and still unsettled. Within the available time-frame, it would not have been possible to complete a statement of articles on a sufficient number of such specific topics to make that exercise useful.

The list of specific bioethical issues need only to be mentioned to indicate the high controversy that they typically involve, including in such topics as abortion, the use of embryonic stem cells, intellectual property rights, euthanasia and so on. This is not to deny the importance of those issues or of the urgent issues of access to healthcare, essential medicines and other special concerns of developing countries. Nevertheless, the controversy of the topics, the absence for the most part of a global consensus and the need to engage in substantial consultation before finalising such principles persuaded the IBC not to attempt that task in the present Draft Declaration.

Instead, provision is made for the follow-up of the present Declaration by IBC and IGBC and by UNESCO itself. The Draft Declaration in its present form adheres to a conceptual unity. It is concerned with general principles and general procedures. For the specific topics, supplementary provision will be needed, either within the scope of the present Declaration, once adopted, or in

different instruments addressing the specific topics but conformably with the principles of the Draft Declaration.

Whilst disappointment at the lack of attention to specifics may be understandable, the time-frame and the integrity of the document and of the work of UNESCO ultimately persuaded the IBC to take the course that has been adopted. I do not doubt that it is the correct course.

8. Precaution and risk assessment: A number of submissions were made to the IBC concerning the importance of including, amongst the principle contained in the Draft Declaration, a so-called "Precautionary Principle". One of the members of the IBC, Dr Roberto Andorno (Member of the IBC, Argentina) has written extensively on this topic and contributed his views to the IBC deliberation³. There was support indeed for a precautionary principle. Such a principle has been included in some regional, and referred to in some international instruments.

Nevertheless, in various respects the precautionary principle has proved controversial. Some Member States of UNESCO have

³ R Andorno, "The Precautionary Principle: A New Legal Standard for a Technological Age" (2004) 1 *Journal of International Biotechnology*, 11. See also by the same author "Towards an International Bioethics Law" (2004) 15 *Journal International de Bioetique* 131.

expressed concern that the precautionary principle could, in practice, constitute an unjustifiable and unnecessarily restrictive interference in scientific and technological developments. The economic implications of the Precautionary Principle have proved controversial and divisive in some circles.

To avoid these concerns but to reflect the undisputable fact that risky endeavours necessitate appropriate responses, the IBC has suggested the adoption of an approach of risk assessment and management which encourages the adoption of procedures to ensure that risks of damage to public health, human welfare or the environment are properly factored into the decision-making relevant to the implementation of the principles of the Declaration. It is hoped that this approach will sufficiently reflect concerns about risks whilst avoiding the divisive international debates about the so-called precautionary principle.

9. *Procedural criteria:* A most important innovation of the Draft Declaration is the inclusion of a series of articles concerned with the conditions for the implementation of the principles. These articles deal with such issues as the making of decisions; the carrying out of practices with independence, honesty and avoiding conflicts of interest; with transparency and through processes of fair decision-making; and allowing for periodic review.

There has not before this been an attempt to collect such basic methodologies and to state them in an international instrument. In a sense, these provisions represent rules of good governance both for States and for institutions and individuals concerned. It is a common experience that if proper procedures are observed - such as observance of fair decision-making practices; avoidance of conflict of interest; and adoption of transparency - the consequent outcome will be more sound than where the procedures adopted are purely *ad hoc* and dependent upon individual predilection.

Originally, the IBC included these practices amongst a sub-category of so-called "Procedural Principles". It then emerged that use of the word "procedural" presented difficulties. In some languages that word attracts a connotation of judicial or legal "procedure". Hence, although not described as Procedural Principles, the criteria stated for the implementation of the principles of the declaration constitute an important value-added. They bring to the notice of all relevant decision-makers - and specifically ethics committees and other such bodies (however described) which will have functions to implement the proposed Declaration - the basic criteria to be observed in implementing the Declaration's principles. This is undoubtedly an important innovation of the Draft Declaration.

10. Place for the biosphere: A common issue in contemporary discussion of the principles of bioethics is the need to make bioethical decisions, and carry on bioethical practices, with proper regard to the interests not only of human beings but also for biodiversity, the environment and the biosphere.

By coincidence, the January 2005 meeting of the IBC and the IGBC has coincided with a major UNESCO conference on the biosphere. The presence in the UNESCO Headquarters of these two contemporary projects underscored their close inter-relationship. Whilst the proposed Bioethics Declaration is substantially addressed to the concerns of human beings and anchored in notions of human dignity, human rights and fundamental freedoms, a number of references are intended to remind the relevant decision-makers of the special responsibility which human beings have for the protection of biodiversity and the biosphere. The inclusion of this reminder amongst the principles of the Declaration is an important corrective to a purely anthropomorphic or human-centered notion of bioethics.

Because it is concerned with life itself ("bio"), contemporary bioethics has a wider focus than purely or exclusively human concerns. Humanity exists in the context of other life forms and many contemporary bioethical decisions, practices and issues are concerned with such life forms, including as they affect animal and plant life. The inclusion of reference to this aspect of bioethics does

not exclude the further, specialised and more particular development, in UNESCO and elsewhere, of international instruments concerned with the biosphere and the ethics of scientific activities affecting it.

11. Exceptions and restrictions: In a Declaration, necessarily expressed in general terms, it is impossible to cover all eventualities and to address, in the principles and criteria of implementation stated, every possibility that may need to be considered. The most that can be hoped for (and it is a considerable achievement) is to state the basic principles in general terms.

In this proposed international instrument, as in most such documents, provision is made for the creation of restrictions and exceptions. The concern has been stated by a number of Member States of the need to provide for observance of domestic law. Realism requires recognition of the fact that domestic law, and particularly municipal constitutional law, will, in practical terms, at least initially, prevail in municipal courts, practices and decision-making over the hortatory language of a non-binding international declaration. From the perspective of local decision-makers, at home they will be bound by their national constitutions and laws.

Nevertheless, it would be inappropriate to provide a blanket exception for domestic law. The purpose of a Declaration such as

the present, is to encourage and promote the crucial principles it espouses.

That is why such principles are stated in apparently mandatory language ("shall"). Nevertheless, the carrying out of the principles is addressed in the closing articles of the Declaration. Where, in those provisions, the Declaration addresses itself to Member States, it does so in terms of the verb "should". That is the language appropriate to an international instrument in the form of a Declaration. The principles themselves, however, are stated in imperative language because it is intended that they should speak to the world in terms of their individual contents. For implementation and for the procedures for implementation, it is left to the word "should". This recognises the inevitable inter-relationship between the Draft Declaration and municipal law, particularly in the initial phase.

The restrictions and exceptions that may exist in the municipal law of Member States is recognised in an article addressed to that specific topic. Once again, that article follows the usual form. Such restrictions must be "prescribed by domestic law". In this respect, they must be clearly stated and not dependant on administrative *fiat* or whim. But there is an additional requirement, usual to international instruments, that any such domestic law must itself be consistent with international human rights law and necessary in a democratic society in certain specified

and identified interests, such as for the protection of public safety, the prevention of crime and the protection of public health and the rights and freedoms of others.

The Draft Declaration is thus attentive, in an orthodox way, to the proper role of domestic constitutional and specific laws. However, the restrictions so provided must be conformable to the usual international principles. An international instrument, even a non-binding Declaration, must recognise and provide for the need of domestic law that conforms with international human rights law.

12. Follow up and specific topics: Finally, the implementation section of the Draft Declaration includes provision for following up the Declaration and for addressing the many specific topics that have not been dealt with in terms but which are on the agenda of the IBC, following the consultation with the Member States.

In fact, the IBC has already dealt with a number of such specific topics, including as they concern issues of intellectual property rights and embryonic stem cells. More such issues will be dealt with in the future. But now they will be considered within the framework of principles expressed in the Draft Declaration, if it is adopted by the General Conference of UNESCO.

One subject in the implementation provisions that has proved controversial concerns the article providing for regular monitoring of the operation of the Declaration and the provision of reports by Member States on the implementation of the proposed Declaration. Initially, this draft provision contemplated the provision of such reports to the Director-General every two years. As a result of submissions, this was altered to five years. Some Member States have suggested the deletion of this provision. Nevertheless, the members of the IBC consider that a procedure for regular reporting and assessment is a useful means to ensure against the preparation of such documents that are regarded as an end in themselves. Instruments such as the Draft Declaration are only as useful as they prove helpful to Member States and to the other groups, institutions and corporations to whom they are addressed. The growing global attention to principles of good governance and to the application of those principles to international agencies such as UNESCO, suggest that some mechanism for reporting, monitoring and follow-up may be necessary and desirable. The present Draft makes that provision.

CONCLUSIONS

There are many further innovations in the proposed UNESCO Declaration on Bioethics. It will be enriched by the consultations with the IGBC, within the IBC, with the public, non-governmental organisations and various individual experts. It will then be

submitted to the consideration, through the internal processes of UNESCO, by governmental experts and by Member States.

It is highly desirable that the consideration that will follow the completion by the IBC of its task, should be mindful of the faithful attention that has been paid to the suggestions and proposals for change; the sensitive balances that have been struck; the rigorous and transparent techniques of consultation that have been observed; and the explanations given for the terms and structure of the Draft Declaration as it is to be finally submitted.

Whilst the final word must rest with the Member States, gathered in the General Conference of UNESCO, the tradition that has been observed to date, in previous Declarations, has much to commend it. The IBC Draft should not be viewed as a purely provisional document, open to root and branch revision and alteration. The Joint Session of the IBC and IGBC and the previous meetings of the IBC with the IGBC, demonstrate the contradictory character of many State submissions, the multiple interests that are involved, the sensitive balances that must be achieved and the careful processes adopted by the IBC itself to present a Draft of the highest quality.

This review has been designed to demonstrate the transparent procedures that the IBC has adopted and the

substantial achievements which the proposed Declaration on Bioethics will incorporate.

It is appropriate, finally, as a Member of the IBC, to express sincere thanks to the Director-General (Mr Koichiro Matsuura) for his unfailing support for the work of the IBC in completing its task conformably with the wish of the Director-General and with the resolution of the General Conference of UNESCO.

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