Global bioethics at UNESCO: in defence of the Universal Declaration on Bioethics and Human Rights

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The Universal Declaration on Bioethics and Human Rights adopted by the United Nations Educational, Scientific, and Cultural Organisation (UNESCO) on 19 October 2005 is an important step in the search for global minimum standards in biomedical research and clinical practice. As a member of UNESCO International Bioethics Committee, I participated in the drafting of this document. Drawing on this experience, the principal features of the Declaration are outlined, before responding to two general charges that have been levelled at UNESCO's bioethical activities and at this particular document, are outlined. One criticism is to the effect that UNESCO is exceeding its mandate by drafting such bioethical instruments—in particular, the charge is that it is trespassing on a topic that lies in the responsibility of the World Health Organization. The second criticism is that UNESCO's reliance on international human rights norms is inappropriate.

Former United Nations (UN) Secretary General Dag Hammarskjöld often said that the UN was not created to take humanity to heaven but to save it from hell. By this aphorism, he meant that although the UN has its weaknesses and limitations, it has an irreplaceable role in our conflictive world by promoting peace, respect for human rights, and social and economic development. The UN is imperfect because it mirrors the world, with its divisions and disagreements. Nevertheless, it is the only forum where humanity speaks in its entirety and where it is able to express, as best as it can, its collective hopes and convictions.

If we consider the specific domain of bioethics, Hammarskjöld's dictum could be applied to UN agencies that are engaged in this specialty. Although they are not able to guarantee that biomedical advances will always be used for the greatest well-being of humanity, they can at least contribute to prevent their use in a manner that would be contrary to human dignity and human rights. Among the means UN agencies use to achieve their goals (in this case, the promotion of responsible biomedical research and clinical practice), the "standard setting activity" is one of the most salient ones.

It is precisely in such a context and with such an expectation that the Universal Declaration on Bioethics and Human Rights was adopted on 19 October 2005, at the 33rd session of the General Conference of UN Education, Scientific, and Cultural Organisation (UNESCO), by representatives of 191

countries. It is interesting to point out that the drafting process was preceded by a report of an International Bioethics Committee (IBC) working group that considered the feasibility of such an instrument. The working group, chaired by Professors Leonardo De Castro (Philippines) and Giovanni Berlinguer (Italy), concluded by supporting the initiative and affirming the need to develop "a worldwide common sense to foster understanding and cohesion in relation to new ethical categories and new practical possibilities emerging from science and technology".¹ With this background in mind, the IBC, chaired at the time by Mrs Michèle Jean (Canada), prepared the preliminary draft declaration, after almost 2 years of discussions and public consultations with governmental and non-governmental organisations. Justice Michael Kirby (Australia) chaired the drafting group, which was open to all IBC members. To ensure transparency in the process, the successive versions of the document were posted on the internet as they were being developed. In January 2005, the draft was examined by the Intergovernmental Bioethics Committee and, finally, it was revised in two successive meetings of governmental representatives, who introduced several amendments.²

Despite the great number of existing international guidelines, statements and declarations relating to bioethics, the new UNESCO Declaration makes its own remarkable contribution to this topic. It is worth mentioning that this is the first international legal, though non-binding, instrument that comprehensively deals with the linkage between human rights and bioethics. Regardless of the weaknesses inherent to this kind of instrument, the very fact that virtually all states reached an agreement in this sensitive area is in itself a major achievement. It should be noted that most international declarations and guidelines in this topic do not have the status of legal instruments because they have been issued by non-governmental organisations such as the World Medical Association (WMA), the Council for International Organizations of Medical Sciences and other academic or professional institutions. Other documents, although adopted by intergovernmental bodies, cover only specific bioethical issues, such as the UN Declaration on Human Cloning of 2005³ and the UNESCO Universal Declaration on the Human Genome and Human

Abbreviations: IBC, International Bioethics Committee; UNESCO, UN Educational, Scientific, and Cultural Organisation; WMA, World Medical Association; WHO, World Health Organization

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Rights of 1997, or are regional but not global instruments, such as the European Convention on Human Rights and Biomedicine of 1997.

It is important to indicate that the Declaration includes in its section II important substantive principles relating to bioethics, such as:

- Respect for human dignity and human rights (Article 3.1)
- Priority of the individual's interests and welfare over the sole interest of science or society (Article 3.2)
- Beneficence and non-maleficence (Article 4)
- Autonomy (Article 5)
- Informed consent (Article 6)
- Protection of persons unable to consent (Article 7)
- Special attention to vulnerable persons (Article 8)
- Privacy and confidentiality (Article 9)
- Equality, justice and equity (Article 10)
- Non-discrimination and non-stigmatisation (Article 11)
- Respect for cultural diversity and pluralism (Article 12)
- Solidarity and cooperation (Article 13)
- Access to healthcare and essential medicines (Article 14)
- Benefit sharing (Article 15)
- Protection of future generations (Article 16)
- Protection of the environment, the biosphere and biodiversity (Article 17).

Section III ("Application of the principles") is devoted to principles of a more procedural nature such as:

- The requirement for professionalism, honesty, integrity and transparency in the decision-making process regarding bioethical issues (Article 18)
- The need to establish independent, multidisciplinary and pluralist ethics committees (Article 19)
- The call for an appropriate risk assessment and management in the biomedical field (Article 20)
- The need for justice in transnational research (Article 21).

THREE BASIC FEATURES OF THE DECLARATION

At this point, three basic features of the declaration should be emphasised.

Firstly, the principles it contains are formulated in very general terms; the declaration does not give almost any definition of their precise meaning (which are only provided, to some extent, by the explanatory memorandum that accompanied the preliminary draft declaration). This method, which may surprise some, is in fact a common practice in law, in conformity with the old maxim "*Omnis definitio in iure periculosa est*". (Every definition in law is perilous.) Except for very technical terms, lawmakers normally prefer not to define precisely most of the words they use. Rather, they tend to leave that task to common understanding and, ultimately, to courts' interpretation, in order not to be constricted in advance by rigid definitions. In the case of the UNESCO Declaration, this strategy can also be explained for practical reasons, because it would have been impossible to reach a global agreement on the precise meaning of terms such as "human dignity", "autonomy", "justice", "benefit", "harm" or "solidarity", which have a long philosophical history and are, to some extent, conditioned by cultural factors. Thus, the generality in the formulation of the principles can ultimately be justified by the need to find a balance between the universalism of some bioethical norms and the respect for cultural diversity.

A second feature of the declaration relates to the nature of UNESCO itself as an intergovernmental body. This should not be forgotten because it would be a mistake to assess with purely academic criteria an instrument such as the declaration, which is not the exclusive product of academic work, but rather a kind of compromise between a theoretical conceptualisation made by experts and what is practically achievable given the political choices of governments. We need to keep in mind that governments, not independent experts, have the last word in every declaration or convention issued by UN agencies. This is not to say that the quality of such instruments is necessarily affected negatively by the requirements of governments. It is true that the IBC draft was more precise on several points than the version adopted by governmental representatives, as Justice Kirby himself has admitted.⁴ Personally, I regret for instance that the recognition of the precautionary principle as a risk management tool for public health purposes has been removed from the final version of the document. On the other hand, I acknowledge that some of the amendments introduced by governmental representatives really enhanced the declaration, such as the more detailed provision regarding research on people unable to consent (Article 7) and the reference to human vulnerability (Article 8). What I intend to argue here is that the approach to bioethics followed by international instruments such as the new declaration is not only an academic but also a political one, and therefore must be assessed with different, broader criteria.

A third important characteristic of the declaration is its non-binding nature. Like any declaration adopted by UN agencies, the new UNESCO document makes up part of the so-called soft law instruments—that is, instruments that are weaker than conventions because they are not intended to oblige states to enact enforceable rules inspired by the common standards, but to encourage them to do so. This procedure permits states to take on commitments they otherwise would not have taken, because they assume just political obligations that are not legally binding. Furthermore, soft law instruments present the advantage of permitting countries to gradually become familiar with the proposed standards before they are confronted with the adoption of enforceable rules or with the development of a binding instrument—that is, a convention.⁵ In addition, it is helpful to remember that, if the same non-binding standards are reaffirmed in successive declarations, in the course of time they may become binding rules, in the form of customary law and jurisprudential criteria, as it happened with the Universal Declaration of Human Rights of 1948.⁶

UNESCO'S INVOLVEMENT IN BIOETHICS

The following sections of this paper will focus on two serious criticisms that have been levelled against the new declaration. The most fundamental one is the involvement of UNESCO itself in bioethics. The other one relates to the use of a human rights framework to achieve common standards in this discipline.

Regarding the first charge, it has been advanced that UNESCO would be in an "obvious attempt at meddling in the professional domain of another UN agency, WHO" and that "it is entirely unclear why UNESCO should concern itself with such a matter".⁷ Similarly, it has been argued that "UNESCO is clearly overstepping its mandate and encroaching on that of the World Health Organization (WHO)".⁸

In response to these objections, it should be noted, first of all, that a clear-cut division of competences between UN agencies is not always as simple as it may seem at first glance, especially in issues that are at the intersection of different disciplines. Secondly, what is really unclear is why the only UN agency specialised in sciences (both natural and human sciences) and having served for decades as a forum for philosophical

discussion on cross-cultural issues would be excluded from making any contribution to the normative guidance for life sciences. It is helpful to remember here that the purpose of UNESCO is, according to its Constitution, to promote "collaboration among 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".⁹ Is it really then surprising that an organisation with such a mission may be interested in the establishment of some common standards for bioethics?

In addition, it is noteworthy that, since its foundation in the aftermath of the Second World War, UNESCO has been associated in the preparation of some 28 international conventions, 12 declarations and about 31 recommendations, including the Convention against Discrimination in Education (1960), the Universal Copyright Convention (1971), the Convention concerning the Protection of the World Cultural and Natural Heritage (1972), the Declaration on Principles of International Cultural Cooperation (1966), the Declaration on Race and Racial Prejudice (1978), the Declaration on the Responsibilities of the Present Generations Towards Future Generations (1997), the Recommendation on the Status of Scientific Researchers (1974), the Recommendation concerning the International Standardization of Statistics on Science and Technology (1978) and, more recently, the Convention on the Protection and Promotion of the Diversity of Cultural Expressions (2005). Why could the international community not take advantage of this long experience regarding sciences, its cross-cultural effect and its significance for human rights to set up global bioethical standards?

This is especially to be considered when one reflects on the fact that the UNESCO's strong involvement in bioethics is not new. It dates back at least to 1993, when the IBC was established on the initiative of Dr Federico Mayor, Director-General of the organisation at that time. The first task of the Committee was the preparation of the preliminary draft of the Universal Declaration on the Human Genome and Human Rights, adopted in 1997. Thereafter, the IBC worked on the drafting of the International Declaration on Human Genetic Data, finalised in 2003. Additionally, since its creation, the IBC produced about 14 reports on various bioethical issues such as genetic counselling, ethics and neurosciences, confidentiality and genetic data, embryonic stem cells, ethics of intellectual property and genomics, and pre-implantation genetic diagnosis and germ-line interventions. In light of this, the question is: Are there many other global intergovernmental organisations that could claim the same level of experience at the intersection of sciences, ethics and human rights? The answer, at least at this stage, seems to be "no".^{10 11}

In reality, a conflict of competence between two or more UN agencies interested in this matter would be as absurd as a dispute between a philosopher and a doctor over the "ownership" of bioethics. Of course, bioethics does not belong in exclusivity to any of them. As it is by its very nature an interdisciplinary specialty, all related professions (and likewise, all related UN bodies) have the right—and the duty—to make their specific contribution to this emerging and complex domain. It is noteworthy that, in fact, UN agencies have already recognised their mutual interest in this matter and, on this ground, have established in 2003 the UN Inter-Agency Committee on Bioethics with the task of improving the coordination of activities in this area.

Concerning the WHO, there is no doubt that, as it is the specialised UN agency for health, it is to have a major role in the standard-setting activities in biomedical sciences. Nevertheless, as some experts have pointed out, clearly, WHO cannot manage this task alone, for the following reasons:

- The field is growing, rapidly encompassing more diverse and complex concerns, due to its interdisciplinary nature.
- WHO has very limited experience in international health lawmaking.
- Such a task would deplete the organisation's limited resources and undermine its ability to fulfill its well-established and essential international health functions.
- Member states are highly unlikely to limit their autonomy and freedom by granting to WHO alone such an expansive new mandate.
- Decentralisation of the international lawmaking enterprise presents great advantages that cannot be ignored.¹²

Furthermore, beyond the fact that UNESCO and WHO are, after all, composed of the same member states, there is a more substantial reason for favouring simultaneous participation of both UN agencies in the topic of bioethics: their standard-setting activities operate at different levels. While UNESCO tends to produce general normative frameworks of a predominantly philosophical and legal nature, WHO's guidelines are usually more technical and focused on specific health-related issues. Therefore, as the approach followed by both organisations is different, their respective engagement in this matter can perfectly coexist. Moreover, it is to be hoped that sincere efforts will be made to stimulate greater cooperation between both UN agencies, which could be extremely fruitful given their complementary expertise in this domain.

USE OF A HUMAN RIGHTS FRAMEWORK

Another criticism of the UNESCO declaration relates to the use of a human rights framework. It has been reasoned that "human dignity and human rights, both strong features of European enlightenment philosophy, pervades this Declaration" and that UNESCO "chose an ideological framework (human rights) that does not feature particularly prominently in professional bioethical analyses".⁵

In my opinion, these objections are misplaced. It is true that the current notion of human rights has its immediate origins in the insights of the European enlightenment philosophers. But this historical circumstance is not a good enough reason to discard the idea that human beings have inherent rights, just as it would not be enough to argue that Mozart or Bach were Europeans to deny the extraordinary beauty of their works. The relevant question is whether the notion that every human being has an inherent dignity and inherent rights makes sense, no matter where this idea comes from. My personal view on this is that the current widespread conviction that people have unconditional rights simply by virtue of their humanity is one of the major achievements of human civilisation, much more important than any scientific or technical development.

This does not mean to ignore the fact that in many Western nations there has been an excessive emphasis on rights and freedoms for the individual, sometimes to the detriment of family and community values, which are of paramount importance to most non-Western societies. Neither does it mean to disregard the great philosophical discussion on whether, or how, the recognition of universal human rights can be conciliated with cultural diversity. However, the truth is that today these controversies have lost much of their practical significance—firstly, because of the increasing number of non-Western states that are party to international human rights treaties; secondly, because human rights emerge from international law instruments with sufficient flexibility to be compatible with full respect for cultural diversity. Far from imposing one cultural standard, human rights instruments set up a minimum protection necessary for human dignity.^{12 13}

It has to be noted that, paradoxically, some of the most severe criticisms of the universality of human rights come from Western scholars. According to Amartya Sen,¹⁵ these views are often based on a misconception of non-Western (largely Asian) societies, as if people in these countries had little or no interest in their rights and were only concerned with issues of social order and discipline (misconception which is of course well exploited by authoritarian regimes ...). In this connection, it is revealing that the only two papers written by non-Western authors that appear in a journal special issue on the declaration openly contradict the pessimistic view of the journal editorial and have a favourable opinion of the human rights approach adopted by UNESCO.^{16, 17} One of these papers¹⁷ even argues that the universality of the principles of human dignity and human rights ... is not emphasised enough by the Declaration!

Furthermore, the objection that the bioethical discourse is alien to a human rights approach is simply contrary to the facts: many, if not most, international policy documents relating to bioethics issued during the past two decades are framed on a rights-based approach and attach utmost importance to the notion of human dignity. A paradigmatic example in this respect is the Council of Europe's Convention on Human Rights and Biomedicine ("Oviedo Convention").¹⁸ Nevertheless, this is not an exclusive feature of Western instruments. Indeed, about 200 worldwide declarations, guidelines, recommendations, opinions and codes relating to bioethics adopted by very different institutions could be cited in support of this assertion.¹⁹ For illustrative purposes, a few examples can be mentioned. Firstly, the famous WMA Declaration of Helsinki on Research Involving Human Subjects (1964/2000),²⁰ which refers in explicit terms to the rights of participants (paragraphs 8, 21 and 22) and regards the protection of human dignity of research subjects as the first basic principle for medical research, along with respect for their life, health and privacy (paragraph 10).²¹ Secondly, the UN Commission on Human Rights Resolution 2003/69 of 25 April 2003 entitled "Human rights and bioethics",²² which strongly insists on the need to ensure the protection of human rights in this field and makes a recurring appeal to the "dignity of the human being". Thirdly, the various statements of the ethics committee of the Human Genome Organisation (HUGO),²³ which emphasise the need to "adhere to international norms of human rights" and to accept and uphold "human dignity and freedom".²⁴

Why this reliance on human rights to set up global bioethical standards?

The first obvious reason is that, as biomedical activities deal with the most basic human prerogatives such as the right to life and to physical integrity, it is perfectly sound to have recourse to the umbrella of international human rights law to ensure their protection. Despite all its weaknesses, the existing human rights system, with its extensive body of international standards and wide range of mechanisms, represents a considerable achievement of our time. This is why it would be strange that a human rights framework could not be used to protect people from harm in the biomedical specialty.

A more practical reason for this phenomenon is that "there are few mechanisms available other than human rights to function as a global ethical foundation, a *Weltethik*".²⁵ In other words, "the human rights framework provides a more useful approach for analysing and responding to modern public health challenges than any framework thus far available within the biomedical tradition".²⁶

Regarding the idea of human dignity, it can be said that, far from being a useless notion as some have argued,²⁷ it has a key role in international bioethics by providing the ultimate rationale for the norms relating to this discipline.²⁸ Certainly, the appeal to human dignity in international law is neither new

nor specific to instruments dealing with biomedical issues. On the contrary, this notion is at the cornerstone of the universal human rights movement that emerged after the Second World War. However, recent international biolaw instruments emphasise the importance of human dignity in a more powerful way than traditional human rights law. Indeed, the contrast between the background role assigned to human dignity in international human rights instruments and the foreground role assigned to it in international biolaw could not be more impressive.²⁹

The UNESCO Declaration³ inscribes itself in this trend when it places at the top of its principles that of "human dignity, human rights and fundamental freedoms" (Article 3.1). Similarly, when it provides that "the interests and welfare of the individual should have priority over the sole interest of science or society" (Article 3.2). This provision of Article 3.2, which has surprisingly also been criticised,⁷ is in fact included, with almost the same wording, in several international documents relating to bioethics, such as the WMA Declaration of Helsinki (Article 5),¹⁸ the European Convention on Human Rights and Biomedicine (Article 2) and the UNESCO Declaration on the Human Genome and Human Rights (Article 10). Through this provision, the new UNESCO Declaration sought to emphasise a direct corollary of the principle of human dignity: that people should not simply become instruments for the benefit of science, because science is not an absolute, but only a means at the service of the human person. It is indeed hard to see what other bioethical principle could be more fundamental than this one.

CONCLUSION

The Universal Declaration on Bioethics and Human Rights is an important step in the search for global bioethical standards. Like any other international instrument of its kind, it is not free from shortcomings. However, in view of the sensitive nature of bioethical issues, the simple fact that virtually all states reached a comprehensive agreement in this discipline is in itself a major achievement. Certainly, most of the declaration's principles are not original; they are derived from several existing international documents. This is why the greatest merit of this instrument is to gather those principles and to integrate them into a human rights framework. In sum, the purpose of the declaration is not to invent new bioethical principles or to provide the definitive solution to the growing list of bioethical dilemmas. Its main goal is much more modest: to assemble some basic standards to help states in their efforts to promote responsible biomedical research and clinical practice, in conformity with the principles of international human rights law.

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