

Biomedicine and international human rights law: in search of a global consensus

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Abstract Global challenges raised by biomedical advances require global responses. Some international organizations have made significant efforts over the last few years to establish common standards that can be regarded as the beginning of an international biomedical law. One of the main features of this new legal discipline is the integration of its principles into a human rights framework. This strategy seems the most appropriate, given the role of "universal ethics" that human rights play in our world of philosophical pluralism. In addition to the general standards that are gradually being established, a widespread consensus exists on the urgency of preventing two specific procedures: human germ-line interventions and human reproductive cloning.

Keywords Bioethical issues; International law; Treaties; Human rights; Gene therapy/ethics; Germ cells; Cloning, Organism/ethics; Consensus (*source: MeSH, NLM*).

Mots clés Enjeux éthiques; Droit international; Traités; Droits homme; Traitement génique/éthique; Cellule germinale; Clonage humain/éthique; Consensus (*source: MeSH, INSERM*).

Palabras clave Discusiones bioéticas; Derecho internacional; Tratados; Derechos humanos; Terapia de genes/ética; Células germinativas; Clonación de organismos/ética; Consenso (*fuentes: DeCS, BIREME*).

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Introduction

"The struggle for human rights is like an overflowing river that floods down across the valley making the fields ever more fertile" (1). With this simile, an Italian academic illustrates the expanding force of the human rights movement, which tends to cover all new areas in which the dignity and freedom of the human person is in need of protection. Probably the most recent field that needs to be "fertilized" by the principles of human rights is medicine, especially genetics. Rapid advances in this area present new and complex ethical and policy issues for individuals and society, and a legal response is needed to avoid misuse of the new technologies.

The new challenges are so formidable and far-reaching that individual countries alone cannot satisfactorily address them. As science becomes increasingly globalized, a coherent and effective response to the new challenges raised by science should also be global. In addition, domestic regulations in this area can be easily circumvented just by crossing state borders. This is why international cooperation is needed to harmonize legal standards and to establish appropriate mechanisms to ensure that such standards are effectively implemented.

Certainly, the search for common responses to the new bioethical dilemmas is an arduous task. One may even get the impression that it is impossible to reach substantive agreement on such sensitive issues between countries with different sociocultural and religious backgrounds. Fortunately, however, the situation is not as desperate as it might seem. The enterprise of setting common standards in the biomedical field, although difficult, is possible because international human rights law presupposes that some basic principles transcend

cultural diversity. Of course, the major challenge is to identify those universal principles with regard to biomedical issues, but it is possible through promotion of an open and constructive dialogue between cultures. This would explain why international organizations, in which different cultural traditions and values are represented, seem to provide the ideal arena for the discovery of such common criteria.

This situation has been perceived by some international bodies — particularly the United Nations Education, Scientific and Cultural Organization (UNESCO) and the Council of Europe — that have made significant efforts over the last few years to reach a consensus on some basic principles relating to biomedicine. The recent regulatory activity on human rights and biomedicine of both bodies was preceded and inspired by the initiative of various international organizations. The World Health Organization (WHO) (2), the World Medical Association (WMA, which developed the famous Helsinki Declaration on biomedical research), and the Council for International Organizations of Medical Sciences (CIOMS) are perhaps the most important examples.

At present, two international legal instruments in the field of biomedicine are particularly noteworthy: the UNESCO Universal Declaration on the Human Genome and Human Rights (3) and, at the European level, the Convention on Human Rights and Biomedicine, both of which were adopted in 1997 (4). Yet these two instruments are just the first steps towards the elaboration of an international biomedical law: the UNESCO Declaration, which is not a legally binding instrument, focuses exclusively on genetics, while the European Convention, which deals with more general issues,

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is only applicable in the European countries that ratified it. This is why the current situation offers an appropriate opportunity to reflect on the possibility of a universal instrument on bioethics. Some recent initiatives are already moving in this direction.¹

This paper argues for the human rights strategy that characterizes the emerging international biomedical law. It also describes the current consensus on the urgency of preventing two specific procedures: germ-line interventions and human reproductive cloning.

Human rights as a legal framework for international bioethics

Perhaps the two most distinctive features of international instruments relating to biomedicine are the very central role given to the notion of “human dignity” and the integration of the common standards that are adopted into a human rights framework. This is not surprising if we consider that human dignity is one of the few common values in our world of philosophical pluralism (5). Moreover, in our time, a widespread assumption is that the “inherent dignity ... of all members of the human family” is the ground of human rights and democracy (6). It is indeed difficult, if not impossible, to provide a justification of human rights without making some reference, at least implicitly, to the idea of human dignity. This notion is usually associated with supreme importance, fundamental value and inviolability of the human person. In the words of Kant, dignity means that people must always be treated as an end in themselves and never only as a means (7). Of course, attempts to explain and justify human dignity will encounter enormous theoretical difficulties in our post-modern world. However, it seems that, at least for practical reasons, we desperately need this notion if we want to ensure a civilized social life (8). As Dworkin argues, anyone who professes to take rights seriously must accept “the vague but powerful idea of human dignity” (9).

The reference to human dignity in the two aforementioned international instruments is impressive enough that dignity is sometimes referred to in the literature as “the shaping principle” of international bioethics (8, 10). Nevertheless, it should be recognized that dignity alone is unable to provide a concrete solution to most challenges raised by scientific advances. “Dignity” is not a magic word that can simply be invoked to solve bioethical dilemmas. We should explain the reasons for considering that a given practice is in accordance or not with the principle of human dignity. This can enable us to see more clearly why the idea of dignity normally operates through other more concrete notions, such as informed consent, bodily integrity, non-discrimination, privacy, confidentiality and equity, which are usually formulated in the terminology of rights.

Another motive for this strategy is the current worldwide political consensus on the importance of protecting human rights. Like the notion of dignity, but providing a more complete and articulated formulation, human rights can be viewed in our fragmented world as “the last expression of a universal ethics” (11, 12) or as a “lingua franca” of international relations (13).

The global success of the human rights movement in contemporary society is probably due to the fact that a practical agreement about the rights that should be respected is perfectly compatible with theoretical disagreement on their ultimate foundation (14). The Universal Declaration of Human Rights of 1948 is the best example of this phenomenon, because it was drafted by representatives of particularly diverse, even opposed, ideologies. Upon this strong legislative foundation has been built an extensive network of human rights mechanisms designed to develop international standards, monitor their implementation and investigate violations of human rights. Today, the Declaration of 1948 can be considered as “the single most important reference point for cross-national discussion of how to order our future together” (15).

It is true that global bodies often lack the ability to deal with the violations of human rights. In spite of all its weaknesses, however, the current human rights system is the only mechanism available to protect people. This is why the integration of some principles relating to biomedicine into a human rights framework seems fully justified. It should not be forgotten that what is at stake in some bioethical issues, such as human genetic engineering and reproductive cloning, is nothing less than the preservation of the identity of the human species. Thus, it is not an exaggeration to say that we are confronted here with “the most important decision we will ever make” (16). In other words, it seems clear that, in the case of conflict between the preservation of humankind from harm and the protection of purely financial or scientific interests, international law should give preference to the first option (17).

The consensus on two specific issues raised by genetic advances

The emerging global consensus on bioethics is clearly minimalist. When addressing these sensitive issues, international instruments do not pretend to provide a precise and definitive answer to the most intricate questions posed by medicine and genetics. On the contrary, international bodies tend to lay down very general principles like the requirement of informed consent, the confidentiality of health information, the principle of non-discrimination for genetic reasons and the promotion of equity in the allocation of resources in health care, especially to meet the needs of the most disadvantaged populations.

The importance of setting general principles relating to biomedicine should not be understated. General international standards, far from being purely rhetorical statements, may constitute a first step towards promoting more concrete regulations at a national level. It should not be forgotten that national governments, not international organizations, are the primary agents for the realization of human rights.

In any case, the international consensus is exceptionally precise on two specific issues, because it aims to prevent some potential developments that raise the most serious concerns for the future of humanity: germ-line interventions and human reproductive cloning. The lawmaking process, which is usually accused of being too slow to keep up with scientific advances, has on this occasion overtaken science, because legal

¹ On 30 March 2001, the President of France, Jacques Chirac, made a statement to the United Nations Commission on Human Rights suggesting that the time had come to consider the opportunity of a universal instrument on bioethics. In February 2002, the UNESCO International Bioethics Committee set up a working group to provide advice on the same issue.

provisions are being adopted to prevent two technologies that do not yet exist.

Germ-line interventions

The ethical reflections on germ-line interventions usually stress the fact that, unlike alterations of genes in somatic cells, which affect only the treated person, any alteration in germ cells (gametes) or in early embryos before the stage of differentiation would be passed to the next generation. This distinction has serious moral relevance: although somatic cell gene therapy does not raise specific ethical questions, insofar as it does not serve an enhancement purpose, germ-line interventions, given their irreversible effects on future generations and their possible misuse for eugenic purposes, pose unprecedented concerns. This is why most ethical and legal regulations that cover this issue strongly discourage or frankly prohibit this procedure.

At the international level, UNESCO Universal Declaration on the Human Genome and Human Rights provides that germ-line interventions “could be contrary to human dignity” (Article 24). Similarly, the European Convention on Human Rights and Biomedicine states that “an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants” (Article 13).

At the national level, some legal provisions and guidelines that ban germ-line interventions have already been adopted by some countries — mostly developed countries (18). This latter circumstance is not surprising, because human genetic engineering would be possible only where the financial, human and technical means were available. In contrast, developing countries have more urgent problems to solve — such as improving access to basic health care services — before worrying about human genetic engineering. Nevertheless, some developing nations, such as Brazil and India, have also adopted ethical and legal standards on this issue (Brazil Law 8974/95) (19). This is probably due to the mixed situation of these countries, in which a high level of poverty and social inequity coexists with remarkable scientific and technological developments.

With respect to objections to germ-line genetic engineering, it is important to note that they are of a different nature, depending on the purpose of the intervention.

In the case of germ-line interventions for therapeutic purposes — that is, for preventing the transmission of diseases — if we leave aside the controversy on embryo research, the objection is not based on intrinsic ethical arguments, but on the risks of serious and irreversible harm to future generations (20, 27). In addition to this, it is important to recognize that the idea of eliminating “harmful” genes from the entire human population is more utopian than real. Such a global result, if ever possible, could only be realized over thousands of years and with recourse to massive coercive programmes, which would be morally unacceptable (22).

In the case of germ-line interventions for enhancement purposes, the objections are more fundamental and are based on the idea that we do not have the right to predetermine the characteristics of future individuals. That means that people should be free to develop their potentialities without being biologically conditioned by the particular conceptions of “good” and “bad” human traits that were dominant at the time

of those who preceded them. In other words, genetics should not become the instrument for a kind of intergenerational tyranny (23–25). A second objection is that the procedure would profoundly affect our own self-perception as “subjects” — that is, as autonomous beings — which might lead us to consider ourselves as mere “objects” or biological artefacts designed by others (22, 26).

Human reproductive cloning

Since the announcement that a sheep had been successfully cloned from the cell of an adult animal in 1997, concern about the possibility that the same technique could be applied to produce genetically identical human beings has been widespread.

In the debate on human cloning, it is usual to make a distinction between “reproductive cloning” and “therapeutic cloning”. In the first case, the embryo obtained by the cloning procedure is transferred to a woman’s uterus; this begins a process that eventually may lead to the birth of a baby genetically identical to the cell donor. In the second case, the embryo’s inner mass is harvested and grown in culture for subsequent derivation of embryonic stem cells that may have therapeutic applications in the treatment of serious degenerative disorders, such as Alzheimer’s disease or Parkinson’s disease. Although the consensus at the political level is that human reproductive cloning should be banned, no agreement about the ethical acceptability of therapeutic cloning has been reached. In this respect, some have argued that the creation of embryos by cloning for the derivation of stem cells offers such significant potential medical benefits that research for such purposes should legally be permitted (27). Others consider that only embryos that remain after *in vitro* fertilization procedures should be used for that purpose, because they will be discarded anyway (28). Still others are opposed to the use of either cloned embryos or “spare” embryos from *in vitro* fertilization procedures, on the grounds that any deliberate destruction of human life is ethically unacceptable (29). It is evident, therefore, that the value we attach to human embryos remains the key issue in the debate on therapeutic cloning.

At the international level, the most recent initiative aimed at preventing human cloning was taken in December 2001 by the United Nations General Assembly, when it established the Ad Hoc Committee on an International Convention against the Reproductive Cloning of Human Beings (30). This initiative was a response to the request of the French and German governments to the United Nations to approve a worldwide ban on human cloning. The Committee met twice in New York, once in February and once in September 2002 to start the convention process, which is expected to conclude in 2003. The central issue, which remains unsolved, is whether the convention should ban only reproductive cloning or whether it should also include the creation of cloned human embryos for therapeutic purposes.

Other important international instruments that ban (mainly reproductive) human cloning have been adopted by UNESCO, the Council of Europe, the World Health Organization (WHO resolutions WHA50.37 (1997) and WHA51.10 (1998)), the World Medical Association, the European Union and the European Parliament (3, 31–36).

At the national level, many countries have passed provisions that prohibit human reproductive cloning, including France, Germany, Japan, Peru, Spain, Switzerland and the United Kingdom (18).

On the other hand, it is also helpful to consider the arguments, mainly based on utilitarian reasons, put forward in favour of reproductive cloning. Cloning would allow infertile couples to have children who are biologically related to one of the parents and couples who are known carriers of genetic diseases to have children not affected by the risk of such disorders (37). It would allow individuals to “replace” someone of special value to them — such as a child who died prematurely (37). There would be a “right to procreative autonomy”, which would include reproduction by cloning (38, 39). Finally, cloning would allow families or society to reproduce individuals of great genius, beauty or exceptional physical abilities.

Most of the objections to human reproductive cloning are based on the idea of human dignity. Cloning would give the creators unjustifiable powers over clones produced deliberately to resemble an existing individual (or even a dead person) just to satisfy the desires of third persons. In this way, this procedure would become a new and radical form of instrumentalization of people (40, 41). Although human beings cannot be reduced down to just their genes, the fact is that, given their physical similarity to the “original” and to each other, clones might seem like replaceable “copies” rather than irreplaceable originals (42). Cloning is not just another assisted reproductive technology — the cloned child would be without genetic parents and therefore would be irrevocably deprived of the possibility of relating his or her existence to a “father”, a “mother” or a “family” in the normal sense of these terms (43–45). Finally, even on purely scientific grounds, human reproductive cloning is considered to be a dangerous

procedure: data on cloning of animals shows that only a small percentage of attempts are successful, that many clones die during gestation and that newborn clones are often abnormal or die. Such devastating consequences in humans make the procedure ethically unacceptable (46).

Conclusion

The human rights strategy adopted by recent international legal instruments relating to biomedicine seems to be the most appropriate way to manage bioethical issues from a global perspective. Certainly, the search for a global consensus in this area is not free from difficulties, especially because it would be impossible, and indeed unfair, to impose a monolithic, detailed legal framework on societies with different sociocultural and religious backgrounds. This is why the harmonization of principles about biomedical activities must focus on some basic rules. This enterprise seems to be feasible because international law presupposes a hard core of universal human rights. The major challenge today, therefore, is to identify, through a constructive, intercultural dialogue, the universal principles that are relevant to biomedical activities. The current international efforts oriented towards the prevention of human reproductive cloning and germ-line interventions show that new common standards, which take into account not only the interests of present individuals but also those of future generations, are already emerging in this area. ■

Conflicts of interest: none declared.

Résumé

Biomédecine et règles internationales en matière de droits de l'homme : en quête d'un consensus mondial

Les enjeux mondiaux liés aux progrès réalisés dans le domaine biomédical appellent des réponses mondiales. Ces dernières années, certaines organisations internationales n'ont pas ménagé leurs efforts pour définir des normes communes qui puissent être considérées comme les prémisses d'un droit international sur la biomédecine. L'une des principales caractéristiques de cette nouvelle discipline juridique est l'alignement de ses principes sur les droits de

l'homme : une stratégie, semble-t-il, particulièrement adaptée dans la mesure où les droits de l'homme sont la référence universelle en matière d'éthique dans un monde marqué par le pluralisme philosophique. Outre les normes générales qui peu à peu voient le jour, il existe un vaste consensus sur l'urgente nécessité d'empêcher deux opérations bien précises : les interventions sur la lignée germinale humaine et le clonage reproductif chez l'homme.

Resumen

La biomedicina y la legislación internacional en materia de derechos humanos: por un consenso mundial

Los retos mundiales que plantean los progresos de la biomedicina exigen respuestas mundiales. Algunas organizaciones internacionales han hecho grandes esfuerzos durante los últimos años para establecer normas comunes que puedan constituir el embrión de una legislación internacional en materia de biomedicina. Una de las principales características de esta nueva disciplina jurídica es la integración de sus principios en un marco de derechos humanos.

Esta estrategia parece la más adecuada, dado el papel de «ética universal» que los derechos humanos desempeñan en nuestro mundo de pluralismo filosófico. Además de las normas generales que se están estableciendo gradualmente, existe un amplio consenso respecto a la necesidad urgente de prevenir dos métodos concretos, a saber, las intervenciones en las células germinales humanas y la clonación reproductiva humana.

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