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BASIC NORMS OF BIOETHICS: INFORMED CONSENT IN UNESCO BIOETHICS DECLARATIONS*

The purpose of this paper is to assess the informed consent requirements in the Universal Declaration on the Human Genome and Human Rights, the International Declaration on Human Genetic Data and the Universal Declaration on Bioethics and Human Rights. These requirements represent recent international attempts to make informed consent central to ethically and legally acceptable medical and research practices. The author shows that the given standards are minimal and that the drafters failed to make consent and consenting rigorous and a fully specific. Yet, while some national laws have gone beyond these standards, the author reminds that in most countries legislation addressing the social implications of biotechnological developments is either unsystematic or nonexistent. Hence, although not fully determined and included in legally non-binding instruments, the authoritative statements concerning informed consent in the UNESCO declarations represent a very helpful what-to-do list. Moreover, the declarations are the most thorough global initiative thus far to consider human rights implications of biomedical sciences and as such, symbolize an important step in protecting human rights in the area of bioethics.

Keywords: *Bioethics. – UNESCO Declarations. – Informed Consent. – Human Rights. – Human Dignity. – Autonomy.*

In the last decade bioethics has ceased to be only a branch of applied ethics predominantly concerned with establishing what is good and what is bad conduct in medical settings and medical research. To address human rights challenges arising from an increasing number of issues, ranging from abortion, assisted suicide, organ donation to cloning, stem-cell research and genetic engineering, another and no less fundamental approach has been taken *i.e.* a link with human right law has been estab-

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lished and standards to protect human rights in this filed have been set up. Therefore, bioethics also refers to the normative regulation of biomedical activities.[1]

A prominent role in establishing global standards relating to biomedical issues has been taken by UNESCO and its International Bioethics Committee (IBC), established in 1993. So far, all of the 191 Member States of UNESCO have unanimously adopted three bioethics declarations drafted by the IBC: The Universal Declaration on the Human Genome and Human Rights of 1997, The International Declaration on Human Genetic Data of 2003 and The Universal Declaration on Bioethics and Human Rights of 2005.

To decide on complex bioethical issues addressed in these declarations, one need to be well informed about the relevant facts and in most cases has to consider the issue of consent, since consent usually makes unacceptable conduct acceptable. The purpose of this paper is to address and assess the authoritative statements of informed consent in the UNESCO bioethics declarations. These authoritative statements represent resent attempts to make informed consent central to ethically and, one may say, legally acceptable medical and research practice.

Before turning to informed consent requirements set out in the UNESCO instruments, I will briefly recap how the conceptual framework that surrounds the notion of informed consent has become a fundamental feature of modern medicine and medical research.

1. RUDIMENTS OF INFORMED CONSENT

As it is known, informed consent is predominantly judicial construction. However, Justice Cardozo, the most famous founding father of this construction, found the inspiration for his statement that every human being of an adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without patient's consent, commits an assault,[2] in John Locke's teaching that in a civilized society each individual has Property in his own Person.[3] Thus, the seventeenth-century theoretical construction served as basis to launch a judicial concept of informed consent within the common law tradition. Because it is mostly rooted in the value of individualism,

[1] See R. Andorno, "Global Bioethics and Human Rights", 27 *Medicine and Law* 1, 2008, 14.

[2] *Schloendorff v. Society of New York Hospital*, 211 NY 125 (1914).

[3] J. Locke, *The Second Treaties of Government*, in *Two Treaties of Government*, ed. Mark Goldie, Everyman, London, 1993, par.27.

the efforts for establishing informed consent doctrine beyond the Western world has been sometimes charged of "ethical imperialism".

Justice Cardozo's statement from 1914 and the core of the liberal social contract teaching that freely given consent legitimize action that would otherwise be unacceptable have been invoked, reworked and internationally recognized after the WWT. The Nuremberg Code of 1947 is generally seen as the first authoritative statement of consent requirements in biomedical ethics. However, its focus was on research ethics and it did not mention autonomy or information requirements.

The rapid development of biomedical technology and transformation of medical ethics that began in the late 1960s and have continued since then, initiated the extension of consent requirements from research to clinical practice. An evolution took place in the United States through a series of informed consent cases in 1960s and 1970s. By the time bioethics became an international field of study, paternalistic medicine had been largely transformed in the US and patient's rights had been soundly established. The same developments are occurring today in many developing countries where bioethics has more recently become a topic of interest. In these countries, legal guarantee of individual rights, including the patient's rights as well, in the past few decades has been one of the goals of social and political reformers.[4]

Contemporary efforts to make informed consent central to every medical treatment and research seek to raise standards, as well. The Nuremberg standards were open to range of criticism particularly in regard with information requirements and the quality of the consent given.[5] The contemporary standards speak about highly explicit, written and fairly specific consent. Besides the UNESCO's declarations, among many documents aimed at defining adequate standards, one should mention the Declaration of Ethical Principles for Medical Research Involving Human Subjects, better known as the Declaration of Helsinki, and the European Convention which extremely long title is commonly shortened to the Convention on Human Rights and Biomedicine, known as the Oviedo Convention, as well.

Now about substance: why consent is seen to be a goal of modern medicine and what stands for informed consent today?

As to the first, it is a standard view that informed consent aims at promoting patient autonomy and his or her rational-decision making. As to the second, the basic concept is relatively simple: physicians, research-

[4] See R. Macklin, *The Doctor Patient Relationship in Different Cultures*, in H. Kuhse and P. Singer, (ed.), Bioethics*: An Anthology*, Blackwell Publishing, Malden and Oxford, 2006, 2nd, 665.

[5] For more see N. C. Manson, and O. O'Neili, *Rethinking Informed Consent in Bioethics*, Cambridge University Press, Cambridge, 2007, 4 –16.

ers, genetic therapists and other agents have to disclose information about proposed research, proposed medical treatment, alternatives, costs, benefits and risks to patients, research subjects and those deciding whether to proceed with genetic testing, and then they choose or decide which course of treatment or action, if any, to take. In general, the consent must come from a competent person, must be voluntarily given, based on adequate information and the patient must understand the information presented.[6]

It appears that, while one might occasionally encounter a retrograde longing for the day when physicians did not have to go through the process of getting consent, consent is now mostly taken as a standard requirement. This however may not be a complete picture.

First, we know that even in the cultures with a long tradition of seeking and obtaining informed consent, actual consent is not obtained in all cases, and even when consent is obtained, it may not be adequately informed or autonomous. Usually, explicit consent is reserved for more complex or exotic treatments and decisions. It is still common to hear people distinguish between treatments for which consent is required and those for which it is not.[7] In other cultures, the physicians work very much against establishing the informed consent requirements within their medical settings for various reasons, which are usually connected with cultural differences. For example, one physician from Philippines finds informed consent unnecessary in this country, because unlike in the US where patients do not trust their doctors, in Philippines patients place great trust in their physicians.[8] Or, there is a claim that informed consent is incompatible with East Asian principle which holds that every agent should be able to make his or her decisions and actions harmoniously in cooperation with other relevant persons.[9]

On the theoretical level, many question the efforts of making informed consent an ultimate goal of modern medicine. On such views, individual autonomy is only one among a number of important ethical requirements in biomedical practice which is to be balanced against other important principles such as beneficence, non-maleficence, justice etc. Those less radical speak about rethinking informed consent while more radical argue if favor of its abandoning.

Even among supporters, a number of issues have arisen with respect to its application. Most discussions of informed consent in bioethics and medical law focus on two types of issues: (a) – on the disclosure of

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[6] For more see G. J. Annas, *The Rights of Patients*, New York University Press, New York and London, 2004, 3rd ed.

[7] R. M. Veatch, *Abandoning Informed Consent*, in *Bioethics, An Anthology*, ed. Kuhse and Singer, 637.

[8] See in R. Macklin, 665.

[9] *Ibid*., 668–670.

information by those who seek consent and (b) on decision-making by those whose consent is sought.

2. CONSENT REQUIREMENTS IN THE UNESCO INSTRUMENTS

I turn now to my main inquiry: what are the informed consent requirements in the bioethics declarations adopted by UNESCO. I will mostly deal with standards set out in the Universal Declaration on Bioethics and Human Rights because it well illustrates the position taken in all declarations. Besides, this Declaration is of particular importance since it is the first global instrument which takes international human rights legislation as the essential framework and starting point in the development of bioethical principles.[10]

The first point to be made is that Articles 3 to 17 of this Declaration lay out principles that address policy makers, health care providers and different professional groups and bodies with the aim to serve as sources of legislation, policy, and individual decision-making.

A top priority in all actions taken in medical settings and research procedures is given to a request for respecting human dignity. In this way, despite its contested nature, dignity represents a principle of all fundamental rights recognition in the field of bioethics. Thus, informed consent is a concrete manifestation of the principle of human dignity. Closely related to this principle is the principle of autonomy. Respect for autonomy involves not just a respectful attitude but also respectful action. However, autonomy is not simply an invested right. It also has the dimension of responsibility in regard with a decision made and in regard with others. Article 5 declares the right of each person to make individual decisions, while at the same time respecting the autonomy of others.

Accordingly, human dignity, autonomy and responsibility are the basis of informed decisions in the field of bioethics. Article 6 of the Declaration deals with the concept of informed consent in two major fields. Paragraph 1 refers to any decision or practice with regard to medical diagnosis and treatment while paragraph 2 deals with informed consent in the field of scientific research.

In the field of medical practice, the Declaration requires prior, free and informed consent of the persons concerned with regard of any intervention. Note that, neither express nor written consent is specified as a general requirement. On the contrary, the rule is that the consent should,

[10] UNESCO, Explanatory Memorandum on the Elaboration of the Preliminary Draft Declaration on Universal Norms on Bioethics, *http://unesdoc.unesco.org/images/0013/001390/139024e.pdf*, November 5, 2008.

where appropriate, be express, and this would be, as a rule, in cases of more complex treatments and procedures. Although this may appear as a strange solution, the reason for such omission may not be only attributable to differences among national standards. One should bear in mind that such requirements under normal circumstances might demand too much because procedures for explicit and written consent create enduring records of a patient's involvement in consenting procedure. No writing is required to make most contracts, so no written form is required to make consent to treatment valid. A consent form is not *consent* but just some evidence that the consent procedures occurred.[11]

In addition, the Declaration spells out that a given consent does not affect a patient's ability to change his or her mind and windrow consent. Consent may be withdrawn at any time and for any reason without disadvantage or prejudice for the person concerned.

In the field of scientific research, rules are tailored in a slightly different manner. Thus, it is requested for scientific research to be carried out only with the prior, free, express and informed consent of the person concerned. It is accented that the information should be adequate, provided in a comprehensible form and that should include modalities for withdrawal of consent which can be made at any time and for any reason without disadvantage or prejudice for the person concerned. Because of the history of abuse, to protect research subjects' rights, it is made clear that ethical and lawful human experimentation requires the voluntary, competent, informed and understanding consent of the subjects. Note also that in Article 8 of the International Declaration on Human Genetic Data it is emphasized that for the collection of human genetic data, human proteomic data or biological samples, and for their subsequent processing, use and storage, informed consent should be obtained without inducement by financial or other personal gain.

Nonetheless, in the field of scientific research, limitations on the principle of consent are possible and in my opinion, on this point, the drafters of the declarations should have been more specific. For example, in the Universal Declaration on Bioethics and Human Rights it is said that exceptions to consent principle are possible and should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in the Declaration, in particular in Article 27, and international human rights law. Article 27 requests that if the application of the principles of this Declaration is to be limited, it should be done 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. Further requirement is that any such law needs to

[11] G. J. Annas, 129.

be consistent with international human rights law. To remind, the reference to international human rights law is frequently made in the UNESCO declarations. Yet, I believe that such general limitation clause is to loose in the field of medical research. We should not forget that the progress is "*an optional goal*, *not unconditional commitment"*[12] and that the objection that respect for individual sometimes delays scientific advance is insignificant objection. Therefore, to prevent taking advantage of the research subjects, the limitations imposed on their right to consent to medical research should have been listed in a specific terms.

The Universal Declaration on Bioethics and Human Rights speaks about obtaining an additional agreement of the legal representatives of the group or community concerned in appropriate cases of research carried out on a group of persons or a community. However, this does not make an individual's informed consent redundant. It is emphasized that 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.

As it has been shown, if a patient is competent, their consent or refusal of medical treatment is decisive. In contrast, if a patient is incompetent, they may be treated without their consent and therefore it is vitally important to protect their rights and interests. The UNESCO declarations place a chief responsibility for protecting the rights of the persons who do not have the capacity to consent on national states. The domestic law of national states should provide for consent to be given by members of the family, an official or court where the person concerned is incapable of doing so. Yet, some common standards have been recognized. First, once it has been established that a patient lacks capacity, authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned. Second, autonomy principle is not totally abandoned. Thus, 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. International Declaration on Human Genetic Data specifies that the opinion of a minor should be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity.

Knowing that incompetent persons are particularly vulnerable to exploitation in research, the declarations define a number of standards for research that involves such subjects. In these cases, research is based on a principle of beneficence and is subject to the authorization and the protective conditions prescribed by law. In addition, because competent patients are always preferable as research subjects for the reason that they

[12] H. Jonas, "Philosophical Reflections on Experimenting with Human Subjects", 98 *Daedalus* 219, 1969, 245.

can consent on their on behalf, the declarations approve research to involve incompetents only if there is no research alternative of comparable effectiveness with research participants able to consent.

Research which does not have potential direct health benefit for the incompetent patient concerned is also possible but is limited to exceptional cases and with number of steps to be taken to make such research safe and not abusive. Note also that involvement in research is not mandatory. Namely, it is requested to respect refusal of such persons to take part in research.

Finally, it is important to address standards concerning the right not to be informed. Some recent developments in genetics-based medical treatments, including genetic testing and screening, have raised increasing concerns about equal treatment of individuals, their privacy, family relations, labor relations, insurance and intellectual property rights.[13] To address such concerns the International Declaration on Human Genetic Data and the Universal Declaration on the Human Genome and Human Rights promulgate the right of each individual to decide whether or not to be informed of the results of genetic examination, the resulting consequences and research results. Although this concept is sometimes seen as opposing patient autonomy,[14] it is the patient that makes a final decision and in this sense, the right not to be informed represents corollary of informed consent doctrine. However, the declarations fail to provide the conditions for the exercise of this right.

3. CONCLUSIONS

Taken as a whole, the assessment of the informed consent standards specified in the UNESCO declarations has shown that the declarations have proclaimed minimal standards to be followed in the procedure of seeking and obtaining informed consent. Having in mind that some national laws have gone more beyond these standards, it is possible to claim that the drafters failed to make consent and consenting rigorous and a fully specific. On the other hand, one should bear in mind discrepancies among national states. Thus, while in some cultures, the fact that anyone ever considered it acceptable practice to treat an adult without informed consent is found outstanding, in many countries this has been still regarded as an important aim to be achieved. In most countries legislation addressing the social implications of medical and technological develop-

[13] For more see *e.g.* J. Sandor, (ed.), *Society and Genetic Information: Codes and Laws in the Genetic Era*, CEU Press, Budapest and New York, 2003.

[14] See *e.g.* J. Harris and K. Keywood, "Ignorance, Information, and Autonomy", 22 *Theoretical Medicine and Bioethics*, 2001, 415–436.

ments is either haphazard or nonexistent. Therefore, the UNESCO declarations represent a very helpful what-to-do list. In addition, although legally non-binding, the declarations are the most thorough global initiative thus far to consider human rights implications of biomedical sciences and as such, they represent a significant step forward in protecting human rights in this sensitive and rapidly developing area.