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Informed consent in UNESCO's bioethics documents

ABSTRACT

The aim of this paper is to demonstrate, through the analysis of UNESCO's bioethics documents, with special reference to the Universal Declaration on Bioethics and Human Rights and the Bioethics *Core Curriculum*, the spot and role of doctrine of informed consent through its practical application within the systems of biomedicine and health today, as well as through the necessity and importance of international and legal regulations of bioethics.

By finding a foothold in the activities of the UNESCO Chair in Bioethics, whose prevailing topic of educational activities is the topic of informed consent, the presence of multidimensional framework of approaches to resolve issues burdened by moral values present within the health care system is recognized.

Key words: bioethics, informed consent, UNESCO.

Definition of informed consent

Bioethical doctrine of informed consent was not the topic of serious scientific discussions until early 1970s. Ruth Faden, an American scientist from the Kennedy Institute who did her PhD thesis in 1980s on that very topic, defines it as »patient's or research subject's statement that gives a physician or researcher the authorization to carry out specific measures, therapy or to include a subject in a research protocol«. (1). Therefore, it is an authorized activity performed on a patient or a subject by a physician.

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The »corner-stone« of informed consent is the Nuremberg Doctors' Trial and the Nuremberg Code which was constituted in 1947 as a result of the Doctors' Trial (2). Its first point states that the voluntary consent of the human subject is absolutely essential (3).

Elements of informed consent in UNESCO's bioethics documents

Informed consent to a medical intervention is valid only if the person involved in the procedure had previously been informed about the procedure, if the person had understood the given information correctly and has given voluntary consent on this basis (2).

Tom L. Beauchamp and James F. Childress use seven analytical elements, or categories, in their analysis of informed consent:

Threshold elements:

1. competence (to understand and decide)
2. voluntariness in decision-making

Information elements:

3. disclosure of the content of medical information
4. recommendation (e.g. of a treatment plan)
5. testing of understanding of what had been said

Consent elements:

6. decision (acceptance or refusal)
7. authorization (e.g. by signature) (4).

The concept of informed consent is, therefore, based on two basic premises: that the patient has the right to be provided with the amount of information necessary to make an informed decision on the recommended medical treatment and that he or she has the right to accept or refuse the doctor's recommendation. As Ksenija Turković states: »the right to refuse the recommended medical procedure is only the other side of the consent and together they constitute a unit« (5).

Functions of informed consent in clinical practice

According to two prominent jurists and bioethicists, Jay Katz and Alexander Capron, informed consent has following functions:

1. to promote individual autonomy of patients and subjects,
2. to encourage rational decision-making,
3. to prevent the involvement of the public,
4. to encourage ethical self-scrutiny in physicians and investigators,
5. to reduce the danger of civil and criminal liability of physicians, investigators and their institutions (6).

Ivan Šegota proposes that the 6th function should be added here – the communicational function because informed consent is based on communication, it might even be stated that communication is its central issue. From the communicational point of view, in order to establish the validity of the informed consent, it is most important to pay attention to the following:

1. how well is the information communicated,
2. how well is it understood by the patient,
3. how voluntary the consent truly is
4. the manner in which the consent is obtained from persons without the capacity to consent, persons with the reduced capacity and persons exposed to covert pressures (prisoners, soldiers, students...),
5. how much time is spent on communicating with patients or subjects (6).

Bioethics and legal framework of informed consent

Among domestic and international bioethics and legal regulations of informed consent, the following should be mentioned:

- Patients' Rights Act (ZZPP, The Official Gazette 169/04, Articles 6-18),
- Protection of Persons with Mental Disorders Act (ZZODS, Official Gazette 111/97, 27/98, 128/99, 79/02, Article 3, Paragraph 12, Articles 8 and 9),
- Family Act (Article 89/5),
- Declaration of Helsinki 1975 (Articles 9-12),
- UN Declaration on the Rights of the Child 1989 (Article 12/4),
- Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine 1997 (Articles 5/1, 6).¹

¹ Mentioned documents shall not be analyzed in this paper. The author suggests consulting the »Bioethics and Medical Law« Proceedings (7).

Overview of Informed Consent in Unesco's Documents on Bioethics

In analyzing UNESCO's documents on bioethics, there will be a special overview of informed consent in the Universal Declaration on Bioethics and Human Rights, in bioethics *Core Curriculum* and in the Report of the International Bioethics Committee of UNESCO (IBC).

Universal Declaration on Bioethics and Human Rights

In the Declaration adopted by the 33rd General Conference of UNESCO on 19 October 2005 the issue of the informed consent is addressed in articles 6 and 7, which are brought here in full (8):

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be expressed and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
2. Scientific research should only be carried out with the prior, free, expressed and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.
3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

- a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;
- b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Bioethics Core Curriculum

UNESCO's Sector for Social and Human Sciences, Division of Ethics of Science and Technology drew up in 2008 the *Bioethics Core Curriculum* which consists of two parts: *Syllabus* and *Study Materials*. Its main purpose is the education, particularly of medical students. Units 6 and 7 of the *Syllabus* should be singled out from the content (9):²

Unit 6: Consent

Interconnection: human dignity

human rights

autonomy

individual responsibility

The purpose of informed consent

Interrelation between consent and autonomy

Explanation and implementation of consent

² Chapters are based on Articles 6 and 7 of the Universal Declaration of Bioethics and Human Rights.

Exceptions: emergency situations
 minors
 mentally ill patients
 Jehovah's Witnesses
 euthanasia
 HIV patients

Unit 7: Persons without the capacity to consent

Criteria for capacity to consent

Categories of persons without
the capacity to consent: neonates

 children
 confused elderly patients
 patients with learning difficulties
 mentally ill patients
 unconscious patients
 (*Advance Directives, Living Will*)

Legal provisions concerning
consent and capacity to consent: international
 domestic

Procedures: protocols within a health system
 special procedures (surrogate, best interest criterion)

Research on human subjects

**Report on informed consent by the International Bioethics
Committee of UNESCO (IBC)**

The Report was published in 2008 and devoted to Articles 6 and 7 of the Universal Declaration on Bioethics and Human Rights. The International Bioethics Committee (IBC) began its systematic analysis immediately after its publication and in May 2007 it presented this report at the UNESCO General Conference. Taken out from the content of the Report, the following should be emphasized (10):

Content of the information

Conditions of obtaining consent

Manner of expressing consent

Withdrawal of consent

Circumstances of application: clinical practice:

primary medical care

invasive medical interventions

biomedical and clinical research

epidemiological research

public health

emergency situations

organ, tissue and cell donation

Categories of persons requiring special protection

Economic, educational, social and cultural context

International and domestic legal frameworks (role of member countries)

Activity overview of UNESCO Chair in Bioethics at the University of Haifa

The establishment of UNESCO's Bioethics Departments began in early 1990s. So far, eight have been established (11):

- UNESCO Chair in Bioethics, 1994, University of Buenos Aires (Argentina)
- UNESCO Chair in Bioethics, 1998, Egerton University (Kenya)
- UNESCO Chair in Bioethics: »Biojurídica y Bioética«, 1999, University Femenina del Sagrado Corazón, Lima (Peru) s La Sociedad Española de Biojurídica y Bioética, Madrid (Spain)
- UNESCO Chair in Bioethics, 2001, University of Haifa, (Israel)
- UNESCO Chair in Bioethics, 2005, University of Brasilia (Brazil)
- UNESCO Chair in Bioethics, 2005, Ethics and Public Policy Center, Washington D.C. (USA)

- UNESCO Chair in Bioethics and Clinical Medicine, 2007, Instituto Nacional de Enfermedades Respiratorias, México D.F. (Mexico)
- UNESCO Chair in Bioethics, 2007, University of Barcelona (Spain)

The Chair in Bioethics at the University of Haifa should be particularly mentioned. Its field of interest is medical ethics. It was established in 2001 by The International Center for Health, Law and Ethics of Haifa University Law School and the Israel National Commission for UNESCO with the objective to coordinate and stimulate an international Network of Institutes for Medical Ethics Training (NIMED), associating higher education in both the developed and developing countries. It is particularly focused on developing an up-to-date syllabus for medical ethics education which will satisfy the needs and requirements of medical schools throughout the world (12).

Thanks to the Chair in Haifa, on 24 April 2009 the ***UNESCO Unit for Bioethics and Law at the Faculty of Law, University of Zagreb*** was founded. Its first activity was the translation of the book »Informed Consent« (13), edited by Prof. Amnon Carmi, the Chair holder of the UNESCO Chair in Bioethics at the University of Haifa. The Croatian translation, whose editors are Ksenija Turković and Sunčana Roksandić Vidlička, is enriched with translations of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, with the additional protocols of the Council of Europe and the Universal Declaration on Bioethics and Human Rights (14).

Instead of conclusion

The importance attached to the doctrine of informed consent by the UNESCO Unit for Bioethics and Law at the Faculty of Law, University of Zagreb is evident, among other, in Prof. Amnon Camri's words: »The fundamental human rights are based on the acknowledgement of person's status as a human being, the integrity of human life, and the fact that people are born free and shall remain free. The appreciation of individual's values and desires is the responsibility which becomes even greater if an individual becomes vulnerable. Since the autonomy and responsibility of each person, including those who need health care, are accepted as important values, making decisions or participating in making decisions concerning one's own body and health must become universally acknowledged as a right.

Ethical problems arising from a requirement for patient's informed consent are so diverse that it seems appropriate to devote the first from the line of ethics hand-

books to this topic and to acquaint medical students, long before they themselves assume personal responsibility for performing medical duty, with cases that require making, upon the initial diagnosis, ethical, medical and surgical decisions.« (14).

Because, as Ivan Šegota points out: »Informed consent is one of the most important achievements in bioethics... the bioethics corner-stone that divides the new medical ethics from the old one...« (6).

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