INTRODUCTION TO THE SCIENCE OF MEDICAL RIGHTS AND ETHICS – THE MOST RELEVANT INSTRUMENTS

SZILVIA KELLNER*

Medical research is vital to the interests of people, nations and the prosperity and well being of society.[1] Thanks to medical research, many previously incurable diseases can now be completely treated or at least have their ill effects strongly reduced. It is necessary to pay particular attention to this area, as history is rife with cases where doctors abused sick people or performed experiments without a patient's consent. The activity and brutality of Nazi-era doctors is well-known, examining the effects on humans of drowning, cooling and changes in air pressure. Another example is doctors in the USA having observed patients with syphilis that was left untreated. The abhorrent cases mentioned above called attention to the need for the introduction of international regulation of this area, to be strictly interpreted and applied.

The first convention to which this study refers is the Convention on Human Rights and Biomedicine ("Biomedicine Convention").

Relevant Legal Instruments

The Council of Europe (CoE) enacted this agreement in Oviedo on 4 April 1997. The purpose of the convention[2] is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

The preamble lists other conventions that were taken into consideration when formulating the Biomedicine Convention:

i) The Convention for the Protection of Human Rights and Fundamental Freedoms adopted in Rome on 4 November 1950;

ii) The European Social Charter signed by Council of Europe members in Turin on 18 October 1961;

* PhD-student, Széchenyi István University, Faculty of Law and Political Sciences. Email: szilvia.kellner@gmail.com.

[1] From the Hungarian legal literature, see Dósa, Ágnes: Emberen végzett orvostudományi kutatások [Medical Research on Humans]. *Lege Artis Medicinae*, Vol. 12 (2002) No. 6-7, 434., Kovács, Gábor: *Bioetika és büntetőjogi kodifikáció* [Bioethics and the Codification of the Criminal Aspects]. Széchenyi István Egyetem, Győr, 2008.

[2] This convention was implemented into Hungarian law as Act VI of 2002.

iii) Two covenants adopted on 16 December 1966 under the aegis of the UN: the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights;

iv) The Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, signed by the Council of Europe' member states in Strasbourg on 28 January 1981;

v) The Convention on the Rights of the Child, adopted by the UN in New York on 20 November 1989.

Relationship to Other Conventions

The European Convention on Human Rights (hereinafter "ECHR") is referenced in two articles[3] that lay down the foundations for the prohibition of injustice and abuse in the medical profession. Their inclusion was motivated by the appalling history of inhuman treatments in Nazi Germany as well a certain controversial experiments in the USA and the fear that these could be repeated. "Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally …"[4]

"No one shall be subjected to torture or to inhuman or degrading treatment or punishment."[5] All these clauses were violated by the above-mentioned human experiments. Respect for a patient's life, human dignity, integrity and protection of self-determination provide the basis for these rights. No infringement is possible if the patient has given his/her voluntary and informed consent to some kind of intervention. However, during dark days of history, people were indeed treated as mere objects. This situation was considered untenable and the international conventions protecting the human life and health were created as a result.

Both the Article 11 of the European Social Charter (hereinafter "ESC") and Article 3 of the Biomedicine convention imply the right to receive medical care, but while the ESC focuses on prevention, the Biomedicine Convention emphasizes treatment. The International Covenant on Economic, Social and Cultural Rights (hereainafter: "ESCR") and the International Covenant on Civil and Political Rights (hereinafter: "CPR") are similarly closely related to the convention. ESCR Article 12 plays a similar role to the ESC section mentioned above. The right to health appears here as a fundamental human right, being supplemented by a list of detailed, enumerated examples of what signatory states must provide.[6] The CPR states that everybody has

[3] Articles 2 and 3.

[4] Article 2, paragraph 1.

[5] Article 3.

[6] ESCR Article 12 Section 2: „the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; the improvement of all aspects of environmental and industrial hygiene; the prevention, treatment and control of epidemic, endemic, occupational and other diseases; the creation of conditions which would assure to all medical service and medical attention in the event of sickness."

the inherent right to life, that all people are equal before the law and have a right to non-interference with their privacy.[7] Clearly, anybody subjected to any aspect of medical research must be able to provide or deny consent, a decision that must be respected in all circumstances. This means that "consent must be revocable anytime, without justification and harmful consequences". Article 10 of the Biomedicine Convention actually specializes CPR Article 17, with the latter enshrining the right to privacy in general, and the former specifying protection in connection with health related data. In Strasbourg on 28 January 1981, the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data was signed, with the purpose to secure for every individual, whatever his nationality or residence, respect for his rights and fundamental freedoms, and in particular his right to privacy, with regard to automatic processing of personal data relating to him ("data protection").[8]

It is necessary to note very briefly some thoughts about the processing of medical data. Data relating to physical and psychological health may only be handled when the patient gives their consent in writing or when specifically allowed by law. Crucially, a separate area of law deals with the informational self-determination right and the freedom of information for data collection as part of scientific research and treatment. In practice, there is often no time to obtain written consent, since medical treatment and lifesaving procedures need to be performed quickly.[9] What, then, is essential to know about the management and use of sensitive data? In medical research, the use of such data is regulated by two, independent requirement systems. One is the system of measures for the protection of personal data; the other consists of ethical rules for medical research. They are not necessarily consistent.

According to Article 24 of the Convention on the Rights of the Child, a child is entitled to the possible best health care, and medical assistance when necessary for a healthy upbringing. This approach deals with the notions already mentioned above, but there's more: research carried out on children is especially unethical, because it is the child's legal guardian who consents rather than the subject acting independently, despite the child assuming the greater risk. In medical circles it is accepted that children are not simply scaled down adults, but rather have differing physiological functions that influence the absorption rates of medicines and their effects, for example, risking greater damage to health in some cases.

Content and Interpretation of the Convention on Human Rights and Biomedicine

The convention consists of fourteen chapters.

[7] Articles 6, 16, and 17.

[8] Article 1.

[9] Páva, Hanna: *Az egészségügyi adatok védelméről általában* [On the Protection of Medical Data in General] http://www.szoszolo.hu/06tanulmanyaink/230611pava.htm (Szószóló, Alapítvány a Betegek Jogaiért).

The interests and welfare of the human being shall prevail over the sole interest of society or science.[10] This means that medical research must only be carried out on humans if national legislation has adequate regulation in place.

Hungary's law CLIV of 1997 entails regulation of public health. Paragraph 159 (1) implies the following lines and thoughts.

Research on adults with capacity to act can only be conducted if they comply with this law.

In Hungary, that means the purpose of the research must be one of the development of new or improved procedures, better understanding of diceases and pathogens or the gathering of clinical data on the effectiveness and efficiency of medical instruments, at a health facility with infrastructure appropriate for the type of research and its risks. In addition, all of the following conditions must be met:

a) The research plan has been authorized,

b) Preliminary studies have proven the effectiveness and safety of the factors being applied,

c) There are no alternative procedures with effectiveness comparable to human research,

d) The risks to the person in the course of the research are proportional to the expected benefits of the research and the significance of its aims;

e) The subject of the research has consented in writing to the research. If this is impossible due to illiteracy or disability, then oral consent is required before two witnesses with no interest in the research. The declaration of oral consent must be put into writing and signed by both witnesses. In case of an oral consenter regaining their ability to write, written confirmation of consent is required before research is allowed to continue. In absence of this, research on that person must stop.

(2) Research exposing the subject's life and physical on psychological health to disproportionate risk must not be conducted.

This relates to Article 27 of the Biomedicine Convention, which states that the treaty lays down minimal expectations, and does not exclude stricter regulation on a national level, which may include vocational provisions.

Data about the subject is a key element of medical research and its use is subject to informed consent. Council Directive 2001/20/EC defines informed consent in a similar way: a decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.

[10] Article 2.

All of Chapter IV of the Biomedicine Convention deals with human genetics, with one particular provision on the prohibition of selection of a child's gender: procedures capable of being used to select the offspring's gender before birth must only be performed for the detection and prevention of serious hereditary diseases. An ethical problem arises here according to *Ágnes Dósa*, in what diseases are to be considered serious enough to justify selecting a particular gender. Selecting a child's gender is dangerous from a demographic point of view,[11] since the deliberate intervention upsets the ratio of males and females born. *"*… Selective abortion has become so widespread, for example in certain countries of Southeast Asia that up to 80 million women are now "missing" from that region according to research estimates. Due to Chinese birth control politics and to customary views favouring men, China has 112 male children for every 100 females, but even India, Malaysia and Singapore far exceed the healthy ratio of 106 to 100."[12] Indeed, in India's economically more developed regions and China's Hubei province it is not unusual for 120 to 130 boys to be born per 100 girls. More recently, the problem of gender selection for economic interest has arisen. It is a statistical fact that men earn more than women in equivalent jobs. Even though unacceptable, economic considerations provide parents incentives for selecting their child's gender. When a male child reaches adult age, chances are that he will be able to take better care of his parents because of his higher earnings than a female child could. As a result, the risk of population gender ratios being upset is real.

"More male children are born in the world than females (107 boy births for every 100 girl births); this shows clearly in the gender ratio for the 0-14 year age group, with only 936 girls per 1000 boys. For those aged 15 to 64, the ratio evens out somewhat (979 women for 1000 men), due to higher mortality of middle-aged men (40-60) – a general trend in developed countries. Combined with the effect of higher life expectancy at birth for women, the ratio inverts for the over-65s, with 1273 women per 1000 men in this age group."[13]

In order to eliminate financial compensation for organ donations, Article 21 was created, prohibiting financial gain for body parts. This is entirely sound. The number of kidnappings would grow by leaps and bounds if profitmaking were permissible – the organ trade would ramp up and stopping it would be near impossible.

The Bioethics Convention is a binding international contract, and the chapter detailing the consequences violating it reflects this. The signatory states' judiciary must sanction violations of the agreement. The European Court of Human Rights may give,

[11] And nowadays, it is crime under the Hungarian Act C of 2012 on the Criminal Code. Section 170 (Altering the Gender of an Unborn Child), which reads as follows: „Any person who performs a procedure for the purpose of altering the gender of an unborn child is guilty of a felony punishable by imprisonment between one to five years."

[12] http://www.ng.hu/Civilizacio/2010/08/Felborul_a_nemek_aranya_a_vilagban.

[13] http://tamop412a.ttk.pte.hu/files/foldrajz2/ch02s02.html.

without direct reference to any specific proceedings pending in a court, advisory opinions on legal questions concerning the interpretation of the Convention.[14]

Committee on Bioethics (DH-BIO)

Set up under the direct authority of the Committee of Ministers, the Ad hoc Committee of Experts on Bioethics (CAHBI), which in 1992 became the Steering Committee on Bioethics (CDBI) has, since 1985, been responsible for the intergovernmental activities of the Council of Europe in the field of bioethics.[15] On 1 January 2012, following the reorganisation of intergovernmental bodies at the Council of Europe, the Committee on Bioethics (DH-BIO) has taken over the responsibilities of the Steering Committee on Bioethics (CDBI) for the tasks assigned by the Convention on Human Rights and Biomedicine as well as for the intergovernmental work on the protection of human rights in the field of biomedicine.[16]

All member states of the Council of Europe, and furthermore, all parties to the Biomedicine Convention outside the Council of Europe, may be represented in the commission and a vote is at their disposal.

The World Medical Association's Declaration of Helsinki and Geneva

Helsinki Declaration

The World Medical Association (WMA) adopted the Declaration in June 1964 in Helsinki. It provides basic ethical principles and directives for doctors and scientists who implement medical research carried out on humans.[17] "Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles."[18] The foundation of both declarations (Helsinki and Geneva) is the individual's freedom and well-being and the weighing of risks versus benefits.

The Declaration of Helsinki adds the principle of research value and the significance of technical and scientific development. The Declaration formulates an important basic principle in connection with placebo-controlled experiments: such experiments may be ethically acceptable even given the existence of proven therapeutic techniques, when due to where absolutely necessary and scientifically sound methodological reasons it is

[14] Article 29.

[15] http://www.coe.int/t/dg3/healthbioethic/cdbi/INF_2012_4%20E%20info%20doc%20dhbio.pdf.

[16] http://www.coe.int/t/dg3/healthbioethic/cdbi/default_en.asp.

[17] http://egk.tatk.elte.hu/index.php?option=com_docman&task=doc.

[18] http://www.wma.net/en/30publications/10policies/b3/.

necessary to determine the effectiveness or safety of a prophylactic, diagnostic or therapeutic procedure; also, where a less significant aspect of a prophylactic, diagnostic or therapeutic procedure is being studied and the placebo recipient subjects are not exposed to a risk of serious or irreversible harm.19 The declaration has been amended repeatedly. The declaration positively formulates the ethical principles of medical research. It firmly states that the patient's health must be paramount for doctors and that the health of the individual should be put before the interests of science, but it also records that research is necessary for furthering science. In all research protocols it should be declared that research is carried out in accordance with the basic principles of the Declaration.[20]

Geneva Declaration

WMA's second general meeting adopted this in Geneva in 1948. "This declaration (…) is essentially a medical oath summarizing general ethical maxims. One of its points specifically refers to the sins of medicine in Nazi Germany: "I will maintain the utmost respect for human life from the time of its conception; even under threat, I will not use my medical knowledge contrary to the laws of humanity."[21]

Good Clinical Practice (GCP)

The International Conference on Harmonisation ("ICH") Steering Committee, which was created by its Expert working group, adopted GCP governing principles in May 1996. Good (Correct) Clinical Practice is the international ethical and scientific qualitative requirement system for the planning of, documentation for and reporting on clinical trials conducted on humans. These requirements ensure that the rights, safety and wellbeing of persons involved in clinical trials are safeguarded – according to the principles of the Declaration of Helsinki – and that trials supply reliable data. The aim of these governing principles by the ICH is to create a common requirement system in the European Union, Japan and the United States for facilitating the mutual acceptance of clinical data.

GCP based on the Declaration of Helsinki clears up essential concepts in the first chapter, lays down basic principles that must be taken into consideration during clinical

[19] http://www.magyosz.org/dokumentumok/Osszefoglaloesz_.pdf.

[20] Kaló, Zoltán – Nagyjánosi, László – Kovács, Gábor – Nagyistók, Szilvia: A klinikai vizsgálatok gazdasági hatásának átfogó elemzése és a hazai versenyképességének javítása [Analysis of the Economic Effects of Clinical Trials and Improving their Domestic Competitiveness]. Syreon Research Institute, 2010. 25 www.syreon.eu/FileContent?id=24.

[21] Kerpel-Fronius, Sándor: *A nürnbergi orvosper ma is élő tanulságai* [Lessons of the Nuremberg Doctors' Trial Still Valid Today]. Szent István Tudományos Akadémia Székfoglaló előadásai, Szent István Társulat, 2007. http://szit.katolikus.hu/feltoltes/Kerpel-Fronius%20Sandor.pdf.

trials. The interests of the patient are highlighted and stand above all else. It also states that any doctor conducting a trial should have expert knowledge and certification.

Institution Supervisory Body/ Independent Ethics Committee

The governing principle prescribes that a body such as these, consisting of a reasonable number of members, must validate research. A minimum requirement formulated is that there be at least five members with at least one of them having a field of interest that is primarily not scientific; moreover, there is need for a member who is independent of the institution where the trial is conducted. They may request, beyond the information granted, that further information be given such data could significantly contribute to the protection of the rights, safety and wellbeing of trial's subjects. The governing principle declares members' rights, their obligations and details the commission's procedures. It is important to write briefly about the declaration found in European Union Directive 2001/20/EC on bioethics.

Directive 2001/20/EC of the European Parliament and of the Council

The Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use was passed on 4 April 2001. The governing principles are also guides for member states to follow, who had implement the Directive into national legislation by 1 May 2004.[22]

The aim of the Directive is to harmonize national regulatory frameworks for clinical trials, which is a considerable task since trials are generally not conducted in one location but in multiple member states. The governing principle coming into force had a positive effect on the safety of clinical trials performed in the EU, on ethical standards and benefited the accuracy and reliability of data, and also had a positive effect on cooperation between national authorities. The Directive refers to the Declaration of Helsinki in its basic ethical principles for research carried out on human subjects.

Conclusion

Among others, the author has dealt with the Convention on Human Rights and Biomedicine, the Geneva Declaration, the Declaration of Helsinki, Good Clinical Practice and Directive 2001/20/EC. These international documents all protect human rights. For national legal systems, the task is for detailed laws to be drawn up that must be equivalent to the international legislation and agreements.

[22] Kovács, József: *Bioetikai kérdések a pszichiátriában és a pszichoterápiában* [Bioethics in Psychiatry and Psychotherapy]. Budapest, 2006. 411. http://real-d.mtak.hu/347/1/Kovacs_Jozsef.pdf.

As we have seen, events throughout history (such as abuses) have motivated the creation of these conventions as a response. Ever evolving situations, creating opportunity for abuses will always surface with the development of medical science. An example is cloning, which is relatively new and has brought up many ethical questions.

STUDIA JURIDICA ET POLITICA JAURINENSIS
2018.1.

Editorial Office

Faculty of Law of Széchenyi István University, Győr, Hungary.

Mail: H– 9026 Győr, Áldozat u. 12. Hungary. Fax: [Hungary: 36]-96/310-336. E-mail: kecskes.gabor@sze.hu

CONTENTS

Issue № 1 volume 5 (2018)

Imprint:

Published by Deák Ferenc Faculty of Law, Széchenyi István University, 9026, Győr, Hungary, Áldozat Street 12.

Responsibility for publishing: dean of the Law Faculty, Prof. Judit Lévayné Fazekas, responsible for editing: Prof. Péter Takács.

ISSN: HU 2064-5902