INTERCONNECTEDNESS OF BIOETHICS AND MEDICAL LAW WITH HUMAN RIGHTS AND INTERNATIONAL LAW

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Abstract

In modern times, protection of the right to life and right to health is becoming increasingly important, as the state of public relations in the field of health and medical care, which serves to protect them, is becoming more complex, commercialized, which makes this area a very serious research object for legal scholars. Scientific and technical development in the fields of biology and medicine, revolutionary achievements, new technologies, in particular, transplantology, human reproduction, genetic engineering, genomics, resuscitation, etc. led to the emergence of new moral and legal problems in the field. This emergence has started few decades ago from development of bioethics and medical law new scientific directions on the basis of increase of human rights protection reflected in different international legal instruments, which form the basis of international law and international convention framework.

Keywords: *bioethics, medical law, health law, human rights, international law, bioethics legislation, international convention framework, right to life, right to health, medical experimentation, bioethics and medical law, law and bioethics.*

Beginning in the 1960s, new sciences such as medical law and bioethics began to develop in the world's leading countries. Over time, many scholars in other countries, including legal experts, have come to realize that these new sciences are an essential part of the system of social harmony, promotion and protection of human rights. The main purpose of medical law and bioethics is to protect the rights to life and health, both of which are fundamental human rights. These rights, which have existed since the birth of man, are protected by the 1948 Universal Declaration of Human Rights and the constitutions of many countries [31]. Life and health are given to each person once by nature, and are considered the highest blessing and values in all societies. These are irreplaceable, lifelong blessings and values that cannot be restored when lost.

In modern times, the protection of these two rights is becoming increasingly important, as the state of public relations in the field of health and medical care, which serves to protect them, is becoming more complex, commercialized, which makes this area a very serious research object not only for medico/biological scientists but also for legal scholars [1; 2; 22; 23]. Scientific and technical development in the fields of biology and medicine, revolutionary achievements, new technologies, in particular, transplantology, human reproduction, genetic engineering, genomics, resuscitation, etc. led to the emergence of new moral and legal problems in the field [15; 24].

Bioethics and medical law began to develop rapidly due to the need for a deeper and more complete interpretation of them, a comprehensive assessment of their benefits and harms to humanity, and the need to strike a balance between them. In 2010, at the opening of the 18th World Congress of the World Medical Law Association (WAML) in Zagreb, Croatian President,

Professor Ivo Josipovic, Dean of the Faculty of Law at the University of Zagreb, said: "The level of development of medical law in the country is a key indicator of the level of development and democracy of the state". At the legislative level in civilized countries, there are no questions about the legal rights of men and citizen, all of which are almost guaranteed. The science and experience of these countries nowadays are mainly aimed at guaranteeing the protection of violated rights [17].

This is well admitted that today there is no democratic country, where the importance of protection of human rights in all spheres of public life, particularly in health and medicine, medico-biological sciences is not recognized. Rights in this area are closely related to questions of bioethics and are based on well-known bioethical principles. The international community has developed its own standpoint virtually for every basic principle. This standpoint is reflected in all international legal instruments.

Humanity has always recognized the importance of scientific development for the benefit of progress and prosperity, but the science itself has traditionally avoided appealing to the law and been subject to self-regulation by the scientific community. However, is it possible to control researchers? Moreover, it is very hard to be correct and ethical in this field in terms of the fact that the rules for research conduction come from a consensus in a given society. This, of course, is possible if this society reaches a consensus and then the government converts the key provisions into law. However, even in this case, the provisions will be general and further legal norms should be adopted for application of these provisions. In view of these difficulties, ethical norms remain in most cases as common provisions. It should be noted that the legal norms, in particular from the criminal sphere, should be applied when the basic values of the society are threatened. Thus, in many countries, reproductive human cloning is prohibited by law and these countries consider this practice being contrary to human dignity and believe that such a ban is not an ethical question.

Strict legal verification is necessary (which is essentially higher than ethics), since ethical standards are simply "social" sanctions that do not guarantee compliance with the law. However, recourse to the international or national legislation is not always the key to the problem. It is difficult to present a set of legislative rules, which will be valuable for everyone, since values and conceptions of life and death are so different in general bioethics.

The first large-scale discussion on bioethics was held in Nuremberg in 1946. The result was the creation of the first international instrument on bioethics, the so-called Nuremberg Code that regulated the conduct of scientific research and experiments on humans. The principles outlined in the Code were not legal requirements and were not binding; they were moral standards. The Code stated the need to adhere to certain ethical criteria while conducting experiments on humans. These criteria were the voluntary consent of the subject, his or her legal capacity as well as requirements of informing the subject about the aims, methods and possible consequences of the assumed experiment. A ban was superimposed on experiments with presupposed lethal outcome for the subjects. An agreement on the condition that there is a possibility of ending the experiment at the request of the examinee was made [3; 4; 11].

The provisions of the Code contained a list of basic, fundamental ethical principles for medical research on humans. However, as important as the first in the human history, an international code of this kind the Nuremberg Code was, it did not have a material effect on the practice of conduction of medical experiments on humans in peacetime because the principles of the Code were not of applicable character. These principles were also not binding and were not directly relevant to the daily practice of medical research [3; 4; 11].

In 1975, Economic and Social Council of United Nations (UN) adopted Report of the Secretary-General "Resolution on the Protection of the Human Personality and its Physical and Intellectual Integrity in the Light of Advances in Biology, Medicine, and Biochemistry" [26]. The enumeration of similar documents - national and international - can make more than one

volume. 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) was adopted by the Council of Europe in 1996 and has a fundamental value for the social practice of regulation of scientific medical and biological activity [8].

In 1976 the World Medical Association (WMA) adopts the Declaration of Helsinki, based on which the ethical guarantee of medical research becomes a prerequisite for conduction of the research. Under the influence of growth of risk factors in biomedical practice in national health care systems separate social structures – the so-called ethics committee or ethics commissions – are formed. The task for these structures is to regulate biomedical research and medical practice for the purpose of prevention of the effects that are adverse to human life and health [34].

The growing interdependence of scientific and social realis of modern biomedicine has created a unique spiritual and practical situation, which in the 2nd half of the XX century has demanded its theoretical development. The term "bioethics" reflects the concept that includes the entire set of social and ethical problems of modern medicine, among which one of the top problems of social protection of the human right to life.

It should be noted that some countries have legislation on bioethics at the national level – the laws on bioethics in France (Bioethics Law), the UK (the Human Fertilization and Embryology Act), Germany (the Embryo Protection Act), as well as at regional level – the Convention on Human Rights and Biomedicine. At present, international principles for medical ethics, including those set forth in the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (adopted in 1984 by the UN General Assembly) are functioning [8; 9; 13; 14; 29].

Today we have a universal legal instrument on bioethics adopted by the UNESCO – the Universal Declaration on the Human Genome and Human Rights. The Declaration does not fall into the category of international conventions, nor in the list of recommendations proposed by the constitution of the UNESCO. It is just a declaration of an international organization. However, as opposed to the WHO guidelines, this declaration was adopted at UNESCO's General Conference – incorporating all (186) of the UNESCO member states. At the same time, this declaration has no formal legislative powers and is of a quasi-legislative nature [33].

The Universal Declaration on Human Genome and Human Rights at the moment is the only international instrument containing ethical guidelines for new branches of science. As name implies, the Declaration takes its place in a series of international legal instruments that protect human rights such as the Universal Declaration of Human Rights (1948) whose legal and legislative power is now internationally recognized [31; 33].

A serious problem is the actual mechanisms of the application of the Declaration. Article 24 of the Declaration points out that the International Bioethics Committee (IBC) should contribute to the dissemination of the principles set out in this Declaration and to the further examination of issues raised by their applications and by the evolution of the technologies in question. The Declaration assigns the IBC as a responsible organization for the application of principles. Thus, a serious point in this regard is the implementation of a corresponding mechanism [33].

There was no single legal act regulating the issues of bioethics until October 21, 2005, when on the 33rd session of UNESCO's General Conference the Universal Declaration on Bioethics and Human Rights was adopted. The Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions (article 1). The Declaration clearly identifies the main bioethical principles as classic ones – the principle of informed consent, the principle of privacy and confidentiality, the principle of nondiscrimination and non-stigmatization (articles 6, 9 and 11); and new principles such as for example the principle of social responsibility (article 14). The Declaration does not merely proclaim the relevant principles, but focuses on their

practical application and calls for "professionalism, honesty, integrity and transparency in decision-making", as well as the establishment of independent and pluralist ethics committees, which would include representatives of various branches of science and technology [32].

In the field of biomedical research at the international level, there are also a number documents of advisory nature that were developed and adopted by the Council of Europe, the World Health Organization, the World Medical Association, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and other international organizations. These documents relate both to the general issues of biomedical research involving humans, as well as more specific issues, such as research on development of a HIV vaccine, appropriate clinical practice in drug studies, protection of databases on health and human genome [30].

Monitoring the compliance with legal and ethical standards in biomedical research that involves human subjects is also carried out by ethics committees that have in their competence: ethical review of applications for named studies, monitoring of their conduct and settlement of emergent disputes.

Thus, in the USA a special department within the Department of Health and Human Services is responsible for biomedical research involving human subjects, and the Food and Drug Administration (FDA) is responsible for studies of drugs. The Civil Rights Division in the Department of Health and Human Services ensures confidentiality and protection of information. Special rules of confidentiality in research involving human subjects have been also adopted by the National Institutes of Health [12].

In Sweden, the Central Ethical Review Board and the Swedish Research Council are created and operate at the national level. The powers of these organizations are established by the Law № 2003:460 of the Ethical Review of Research Involving Humans. Provisions for the protection of personal information contained in the Law on Personal Data № 1998:204, biomaterial banks are regulated by the Law on Biobanks in Medical Care № 2002:297, and genetic studies are conducted in accordance with the law relating to the use of individual genetic technology in medical screening (1991). Control in the first of the last two areas is vested in the National Board of Health and Welfare and the Swedish Research Council that has adopted Guidelines on Research Ethics for the Use of Biobanks; and the Ministry of Health and Social Affairs and the named National Council are responsible for the genetic studies [6; 25; 28].

In Azerbaijan, fundamental changes in understanding the law took place in the 1990s after the independence. As a result of changes in the Criminal Code of Azerbaijan the article on sterilization was withdrawn and several new articles were added, including "illegal placement in a psychiatric hospital" (article 126 (2)) and "disclosure of information constituting medical confidentiality" (article 128 (1)). A list of main professional crimes is remained in the new Criminal Code of Azerbaijan, which came into force in 2001. The article on "disclosure of the information constituting a medical secret" is absorbed by the more general wording of the article "violation of privacy". In the section "Crimes against Life and Health" two new articles are introduced: "compulsion to withdrawal for transplantation of body organs or tissues of a person" and "infection with HIV of a person" [10].

In the Constitution of the Republic of Azerbaijan there is also a specific provision on the right of health protection. This article states that:

(1) Everyone has the right for protection of his/her health and for medical care.

(2) The state takes all necessary measures for development of all forms of health services based on various forms of property, guarantees sanitary-epidemiological safety, and creates possibilities for various forms of medical insurance.

(3) Officials concealing facts and cases dangerous for life and health of people will bear legal responsibility [7].

The mentioned principles are reflected in other articles of the Constitution as well: article 16 (Social development and state), article 27 (Right for life), article 39 (Right to live in healthy

environment), article 37 (Right for rest), article 38 (Right for social protection), at alias. It should be noted that some of the above mentioned ethical standards in addition to the Constitution have already found their place in the contemporary national legislation. Prima facie the following legislation acts are at the issue: "Law on the Protection of Public Health" (26 June 1997); "Law on Blood Donorship and Blood Components" (26 September 1996); "Law on Amendments to some Legislative Acts of the Azerbaijan Republic in Connection with the Application of the Law of the Azerbaijan Republic 'On Transplantation of Organs and (or) Tissues'" (20 February 2001); "Law on Psychiatric Care"; "Law on Education (Special Education) of Persons with Disabilities" (05 June 2001); "Law on the State Care of Persons with Diabetes" (23 December 2003), at alias [5;7;16].

In the chapter 4, article 24 "Patients' rights" of the Law of Azerbaijan on Public Health Protection is stated that "in case of violation of a patient's rights, he can complain directly to the manager or other official of the medical and preventive treatment institution, in which the medical care is provided, to respective executive bodies, or to court" [5, 18-21].

Recognizing the importance of judicial protection of patients' rights, special ways of protection at the same time should not be overlooked. Unfortunately, to date, it must be noted that specified in the legislation general and special ways of protection of patients' rights are not adequately spread. This is largely due to the fact that officials of the health care institutions do not pay enough attention to the development and testing of effective mechanisms for the realization of officials' essential function – protection of patients' rights.

Attempts of the modern Azerbaijani law to replace moral regulation, dooms the legislation to the loss of its functions – regulation, observance and protection of the interests of all members of the society. For example, according to the article 36 of Russian Federation' "On the Fundamentals of Protection of the Public Health" Federal Law No323-FZ, "every woman has the right to decide the question of motherhood"[27]. This example can be regarded as a manifestation of a fundamental discrepancy between laws and moral values; differences of law and morality. That is why in many countries of Europe and America, along with detailed legal regulations, there are ethical codes for professional medical associations.

In this regard, it seems urgent to use the world experience in protecting patients' rights, taking into account national specifics of Azerbaijan.

It should be noted that the main obstacle in implementation of the above-mentioned human rights, is clearly insufficient knowledge, primarily by the medical staff, of the content of the patients' rights. At the same time, the importance of this knowledge is understood by the medical professionals in developed countries, where control of human rights in health care has become as stringent as in other areas of human relations.

To conclude few important statements seem to us need to be underlined:

1. As a result of the rapid scientific/technological revolution and globalization in few recent decades, new technologies, approaches, diagnostics and treatment methods have begun to enter the fields of health, medicine and biology. This, in turn, has changed traditional ethical norms and revolutionized the centuries-old relationships in the health sector making it one of the fastest-growing fields of the economy, business and commerce, where there is a great need for legal regulation of these new relationships.

2. Medical law and bioethics are closely related to international law and human rights as modern scientific disciplines. The protection of human life and health is one of the most fundamental, ancient and fundamental human rights, which are the primary responsibilities of medical law and bioethics. Since these human rights and bioethical principles enshrined in international law are closely linked, the formation of medical law and bioethics in the legal science system of Azerbaijan must begin with the platform of international law, human rights.

3. Establishment of bioethical norms by themselves cannot be considered sufficient anymore. Clear legal mechanisms need to be developed to ensure real implementation of them.

4. Medical law has become an integral part of modern jurisprudence system. Medical law must have a place in the system of law sciences in democratic states. Azerbaijan should also include medical law in the system of national law sciences, increase work on development of health legislation, strengthening medical law and bioethics education for future lawyers and medical professionals, as well as support medical law and advocacy in health system and court proceedings.

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