

The Development of Bioethics in Ukraine

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Bioethics is a scientific field that attracts the attention not only of scientists and physicians, but also of people belonging to all sections of the population. Since bioethics is a system of thought, ideas, norms and values which regulates people's behaviour and relationship with every living thing, its role in society is growing. Bioethical issues become clearly multidisciplinary as they cover all major areas of human activity—starting with environmental protection actions and ending with political decision-making process. Ideally, bioethics establishes a set of ethical principles, standards and rules that are universal and compulsory for all mankind, as well as helps to determine the redline threshold to human intrusion into living nature. During the last few decades, ethical issues have become increasingly understood within scientific, social and political circles, starting with modern medicine and biology. The urgency for a wider understanding and application of bioethics is a result of a number of scientific discoveries such as the demonstration of fundamental possibility of human cloning, mapping on the human genome, as well as a widespread introduction of totally new biomedical technologies into medical practice.

In the past Ukrainians took notice of ethical issues in the field of healthcare as well as in the general humanistic and philosophical context of bioethics. Prominent figures in the field of medicine (M. Maksimovich-Ambodik, D. Samoilovich, M. Pirogov, V. Obraztsov, F. Yanovskiy, D. Zabolotnyi, A. Bohomolets, P. Kostiuk, N. Amosov and many others) not only adhered to high ethical standards and rules, but also developed and improved them. They applied new diagnostic, treatment and prevention techniques only after thorough examination on animals and often on themselves. It was typical of them to serve people without seeking profit, to sacrifice themselves in implementing their

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duties. A vivid example was Professor Feofil Gavrilovich Yanovskiy (1860–1928) who was called “the saint doctor” by the Kievites. A reflection attributed to him says: “Everybody has equal rights for earthly blessings. I cannot start living a selfish life and not pay attention to what’s going on with other people who may need my help; I cannot do so not because I’m kind, but because it is unfair to behave this way.”

A modern state governed by the rule of law is involved in the implementation of bioethical standards, the search for the development of a sound bioethical theoretical basis, for solutions addressing bioethical issues, as well as the development of legislation to implement these solutions. It is believed that one of the main prerequisites for the development of bioethics is the establishment of a network of bioethical committees at different levels. At the same time, the coordination of their work assures the implementation of internationally adopted standards and rules in the context of biomedical research, the establishment of a system for ethical education and the organisation of public discussions on the most drastic and key bioethical issues.

As we know, the International Bioethics Committee of UNESCO was created in 1993, and national ethical committees started being organised in many countries as a result. In this context, the National Academy of Sciences of Ukraine (NASU) established a Bioethics Committee which would be attached to the Academy. This was appropriate because a number of national, interagency and international centers, commissions and committees in various fields were attached to the NASU. NASU also had extensive experience in organising interdisciplinary scientific institutions similar to what a new Bioethics Committee was believed to become. In 1998, the committee was created. Prominent scientists from NASU working in the fields of biology, medicine, philosophy and law as well as representatives of various ministries—health, environmental protection, science and education, justice, foreign affairs, and of the Academy of Medical Sciences and the Academy of Agricultural Sciences—became engaged in the Committee’s activities.

Since the very beginning, the Committee actively participated in the development of respective legislative acts in the belief that the implementation of ethical standards and rules greatly depended on such legislation. The Committee members contributed their expertise to new bioethical laws and suggested amendments to the related existing laws. In particular, they carried out an analysis of the compliance of Ukrainian legislation with the provisions of the Convention on Human Rights and Biomedicine and developed the draft law of Ukraine “On Bioethics and Bioethical Expertise” and the draft “Concept of State Policy in the Field of Bioethics”. In addition, they worked over the draft

law of Ukraine on the “State System of Safety during the Development, Testing and Practical Use of Genetically Modified Organisms”. At the request of the Verkhovna Rada (Parliament) of Ukraine, they conducted a review of the law of Ukraine “On Legal Foundations and Guaranties for the Implementation of Bioethics”. At the request of the Ukrainian National Commission for UNESCO, they examined the draft UNESCO Universal Declaration on Bioethics and Human Rights, which resulted in the development of respective suggestions to and comments on it. Committee members took an active part in drafting the model law “On the Protection of Human Rights and Dignity in the Context of Biomedical Research”, which was approved by the CIS Inter-parliamentary Assembly as a basis for the adoption of respective national legislative acts.

Unfortunately, this model law as well as the draft law “On Legal Foundations and Guaranties for the Implementation of Bioethics”, which were developed by the CIS Inter-parliamentary Assembly, though they had been discussed at the public hearings, were not adopted as laws in Ukraine. The list of shortcomings in the Ukrainian legal system in the field of bioethics includes not only the insufficient and fragmentary character of the Ukrainian legal base, with frequent contradictions between different regulatory acts and a lack of consistency in law-making, but also an inefficient human rights system and absence of practical tools for people to implement their rights as declared by the Constitution of Ukraine. For instance, the situation in the healthcare system in Ukraine is most urgent and dramatic. Most Ukrainians do not have access to free medical aid which is “guaranteed” to them by the Constitution of Ukraine. Official low salaries of medical professionals working at state-funded healthcare establishments, the rudimentary level of the development of a health insurance system, a lack of mechanisms coordinating the harmonised operation of state and private medical clinics, and numerous economic and social problems created the preconditions for “double standards” and for the growth of “shady business” in the Ukrainian healthcare system. The relations between the physician and the patient that required several years to build, the image of a physician as a person who is highly humane and endowed with a noble mission and authority, suffered the most. The way out of such a situation could be the introduction of immediate and radical reforms throughout the healthcare system in Ukraine including the key element—the implementation of bioethical principles and standards in Ukrainian law and biomedical practice.

The system for clinical trials of medicinal products represents an important component of the mechanism to guarantee their safety for consumers. As a result, NASU’s Bioethics Committee always paid and continues to attend to

the development of standard operation procedures (SOPs) and their implementation in the ethical expertise of biomedical studies. As part of the activities of the Forum of Ethics Committees in the CIS countries and with the participation of the Ukrainian Bioethics Committee members, the Collected Model SOPs for the Ethics Committees in the CIS Countries was compiled (St. Petersburg, 2004) incorporating the introduction of high international standards in the bioethical expertise process in the region. In order to implement these standards in practice, the Committee participated in the organisation of the following seminars: “Development of the Recommendations for Application of Standard Operational Procedures in Ethical Expertise of Biomedical Studies” (Kyiv, 2004); “The Development of Standards for Ethical Expertise as a Road to the High-Quality and Responsible Practice in Biomedical Research and Healthcare: Experience of Central and Eastern Europe” (Kyiv, 2006); and others. As a result of these activities, an adapted version of standard operation procedures was compiled and is currently used in the ethical expertise of biomedical researches in Ukraine.¹ At present, in order to further improve the ethical expertise system using the standardised and adapted standard operation procedures, a system for the accreditation of local ethics committees is being developed, a register of bioethics committees and commissions attached to various agencies has been compiled, trainings for their members are being prepared, as well as other related measures.

Due to the activities of ethics commissions and committees, bioethics is practically implemented and becomes an effective tool for harmonising social relations in the field of medical practice as well as an indispensable factor in biomedical research studies conducted; not only on humans, but also on animals. The principal functions of the committees conducting ethical expertise of clinical and other biomedical studies are to ensure the safety, well-being and implementation of the rights of those being tested; to monitor the process of obtaining people’s informed consent for their participation in trials; to evaluate the risk-benefit ratio associated with a research; and to ensure the humane treatment of experimental animals. NASU’s Bioethics Committee coordinates the operation of ethics commissions attached to other agencies as well as of bioethics committees conducting ethical expertise of research projects, grants, articles etc. established at all NASU’s biological institutions. Local committees are provided with scientific and methodological support including those required for their experimental studies on animals. Lately, following the requirement from the Highest Certification Commission of Ukraine to conduct obligatory expertise of the research thesis in medicine, biology and veterinary sciences, the role and responsibility of bioethics committees considerably increased.

An important role in the development of bioethics in Ukraine is attributed to the establishment of the Bioethics Committee at the Presidium of the National Academy of Medical Sciences (NAMS) of Ukraine in 2000 as well as to the development of the Standard Statute of Medical Ethics Committee at the Scientific Institution of the NAMS of Ukraine which stipulates goals, tasks, structure, organisation and principles of operation of this committee. By the end of 2001, in all NAMS' institutions, the respective committees have been established. Major results of the activities of the Bioethics Committee at the Presidium of the NAMS of Ukraine worth mentioning include an ethical expertise system within NAMS's scientific institutions to ensure the introduction and implementation of bioethical principles in biomedical research.

It is also worth mentioning that in Ukraine there are several public organisations actively working in the field of bioethics. The first all-Ukrainian NGO aimed at the promotion of bioethical ideas in Ukraine was the Ukrainian Association of Bioethics which was formally registered in 2000 and gathered philosophers, biologists, medical professionals and civil society activists of Ukraine. Another bioethics association, in Kharkiv, was established in 1999. It brought together professors, lecturers, tutors and students of higher educational institutions, as well as scientists and other employees of research and science institutions, and also representatives of other NGOs. In 2001, in Lviv, an NGO named Ya. Basylevich Institute of Bioethics was established, which is attached to the Danylo Galytskyi Lviv National Medical University. Representatives of the senior staff of the university, the Christian Church and youth NGOs are among the members of this NGO.

Currently, the Association of Psychiatrists of Ukraine, Kyiv Ecological and Cultural Center, Kharkiv Society for the Protection of Animals, All-Ukrainian Council for the Protection of Patients' Rights and Safety, Ukrainian Medical Association and other organisations are discussing the relevance of bioethics to their professions. Their tasks include the preparation of recommendations on bioethical expertise, elaboration of proposals concerning legal regulations in the field of bioethics, participation in the international cooperation in bioethical issues, coordination and monitoring of activities conducted by bioethics commissions and committees attached to the state agencies, dissemination of information, and public education concerning current problems in the field of bioethics.

National and international seminars, conferences and symposia play an important role in bioethical training and public education. The National Congress on Bioethics (2001, 2004, 2007, 2010, 2013) confirmed the importance, urgency and need for activities targeted at the promotion of bioethical principles in

Ukraine. The Congresses brought together scientists, specialists, representatives of various confessions and NGOs not only from Ukraine but also from all CIS countries, as well as from several European, American, African and Asian countries. A major result of the 1st Congress was the development of the “Ethical Code of a Ukrainian Physician” and “General Ethical Principles for Experiments on Animals”. As a result of the request expressed in the resolution of the 2nd Congress, the obligatory bioethical expertise of doctorate and candidate thesis in clinical and experimental medicine, biology and veterinary science was introduced.² According to the recommendations of the 3rd Congress, The Ethical Code of a Ukrainian Scientist was developed and then adopted by the General Assembly of the NAS of Ukraine.³ The 4th Congress alerted the attention of the scientific community and general public to the priority of urgent examination of safety issues in the introduction of nanomaterials and nanotechnology. Following the decisions of the Congress, international seminars “Nanotechnology Ethics and Nanosafety” are being conducted in Kyiv on an annual basis. The 5th Congress noted that currently biosafety and bioterrorism are the most urgent bioethical issues. In addition, there were concerns expressed about the alarming situation in the Ukrainian pharmaceutical market, particularly in the field of clinical trials of pharmaceutical drugs and the aggressive advertising campaigns of medicinal products.

Despite successes achieved in the development of bioethics in Ukraine, there are still many problems which have not yet been solved. First are legal regulations in the field of bioethics. The primary problems faced by ethical committees in Ukraine as well as in other CIS countries are related to their institutional establishment (both structural and legal), guaranteeing their independence, building the hierarchy and relationships between different committees and commissions, and providing training to the members of ethical committees. Unfortunately, in Ukraine, there is still no system for the training of ethical committee members: there is no standard training programme, there are virtually no periodicals, and there are very few special publications devoted to the protection of trial subjects and ethical expertise. At the same time, new requirements for ethical expertise necessitate the need to increase the effectiveness of existing local commissions, to organise regular staff training, and to continue legal and standard-setting regulations of the operation and interaction between ethical committees and commissions at different levels. Addressing these issues is the major task for the Bioethics Committee of NAS of Ukraine. In general, there were, and still are, two priority issues on the current agenda of the Committee: first, to set up the systemic operation of already established local ethical committees and second, to support the establishment of new committees.

Today, in most developed countries, not only biomedical research, but also medical and social, epidemiological and environmental projects are subject to ethical expertise. In these countries, ethical committees are established in order to ensure public control over various new technologies and materials (genetically modified products, food additives, pesticides etc.). In Ukraine, the recommendations for ethical expertise were also developed to evaluate research and science projects conducted in nature and biosphere reserves, national nature and landscape parks.⁴ However, the practice of ethical expertise is not sufficiently widespread and is not supported by the society at large. In Ukraine, until recently, ethical committees were a kind of innovative tool for the evaluation and regulation of social relationships in such areas as healthcare, research and science, nature protection etc.

In recent years, public awareness of the development and application of nanomaterials and nanotechnologies has been steadily increasing. Indeed, nanotechnologies are galloping to win the first place in the field of science and technology. They already find their role in very different fields of industry, medicine, ecology, energy, military, information and telecommunication spheres as well as in people's daily life. Various aspects of nanotechnology became a subject for scientific and public discussions.

Since the effects of nanotechnologies and nanomaterials are unpredictable, it is necessary to thoroughly investigate the mechanisms of their action on a molecular level, their related potential toxic effects, as well as to find ways to eliminate or at least minimise undesirable effects caused by them. It is quite logical that the abovementioned issues should attract the attention of scientists and professionals in a wide variety of fields. Scientific personnel training provided by universities and other educational institutions in advanced nanotechnology, covering all aspects of this field, plays an important role in the development of this area. Special attention should be paid to the training of personnel not only in technologies (molecular biology, physical chemistry, materials science etc.), but also in ethical and social issues (p. 84).⁵ A balanced approach to, along with realistic expectations and assessments based on the priority of a safe environment and personal and social safety, are the guarantees of success in the implementation and correct application of nanotechnologies. The assessment of ethical issues related to the surge in nanotechnology must be carried out with strong public involvement. This would help to create a better understanding of their advantages and shortcomings.

In Ukraine, a lot of attention is focused on the elaboration of the fundamentals of nanotechnology and the development of a wide range of nanotechnologies, as well as on the creation of new nanomaterials and nanostructures.

In the context of the combined NASU's programme entitled *Fundamental Issues of Nanostructural Systems, Nanomaterials, and Nanotechnologies*,⁶ more than 100 scientific projects are being carried out in the five following areas: physics and diagnostics of nano-sized systems, chemistry of nanomaterials and nanostructures, fundamentals of nanomaterial technologies, biological nanosystems, and IT support for research in the field of nanosystems, nanomaterials and nanotechnologies. Today, it is obvious that such technologies have an enormous potential and provide great opportunities to exert an influence upon individuals and society. For instance, according to expert projections and estimates, it is the development of nanotechnologies that will make it possible to achieve breakthroughs in medicine, pharmaceuticals and biotechnology, and will help to improve the quality of the environment (p. 89).⁷ At the same time, there are only 20 biomedical projects included in the Academy's programme, out of which only a few address ethical issues and the safety of application of nanotechnologies.

The State Task Programme for Scientific Research and Technology Nanotechnologies and Nanomaterials⁸ includes preparation to further introduce new research developments in the physics of nanostructures, nanostructure semi-conductor technology, diagnostics of nanostructures, nanomaterials, nanobiotechnologies, nanochemistry, and also provide support the development of the nanoindustry. However, only a few projects are devoted to biomedical research, and even these scarcely include studies on the potential risks and safety of nanomaterials. Unfortunately, we should note that nanotechnology legal issues are left totally out of the programme's perspective.

It is correct to believe that human rights, personal safety and health must prevail over scientific and social interests, and thus should be a priority in legislative regulation. However, at present, there are practically no special rules to regulate the state-of-the-art nanotechnology and nanomaterials. Most of the state regulatory agencies that lack legal and scientific tools also do not have information about specific features of these technologies (p. 20).⁹ In general, the response of modern society to the emergence of new technologies and associated new products is very slow; the development of standards and procedures to regulate the use of such products lags well behind.

The situation is ambiguous (this applies not only Ukraine): while proper legal regulation is absent (until now, there is no adequate law on the development and use of nanotechnologies that would regulate the legal responsibility for failure to comply with environmental safety requirements, and the necessary technical regulations have not yet been fully adopted), scientific research is being actively carried out, and nanoproducts produced are released onto the consumers market. Moreover, the abovementioned gap cannot be filled by making relevant

amendments and additions to the legal acts already in force, but require appropriate regulations.

The recently adopted the “Ethical Code of a Ukrainian Scientist” and the “Ethical Code of a Ukrainian Physician” introduce common standards which can be applied in nanosciences based on the specifics of these sciences. Concerning the development and practical application of nanotechnologies, respective laws should be adopted to regulate this field to ensure the observance of human rights and environmental safety. An absence of a proper regulative base, a lack of legal awareness in those who are developing nanotechnologies and in the general public, and often legal nihilism—all call for the revision of a number of state legislative acts that would take into consideration new scientific perspectives, and their relationship with human rights and environmental safety requirements in the context of the development of nanotechnologies and nanomedicine. In order to effectively address ethical and legal issues associated with nanotechnologies, a regulative legal system should be created and a relevant model of state control over this field of activity should be adopted (c. 20).¹⁰

Policy development in the area of scientific developments at large and particularly in the field of nanotechnology, should be started by expanding research in ethical, legal and social issues related to the new scientific areas. Using a collective consultation process, it would be possible to develop certain guideline principles for ethics in science and nanotechnologies and to suggest them as possible ethical frameworks to scientific establishments, corporations and legislative bodies that would, in particular, foster the development of national legislation. The hierarchical system of national, regional and local ethics committees, more or less available in practically all countries can be used to coordinate this process.

From our perspective, in healthcare, research and higher education, in the field of ecology and the preservation of natural resources, bioethics can and should become an alternative to the paradigms of biologism, sociologism and anthropocentrism. At the same time, it is necessary to reconsider creatively forms and methods of bioethics on the basis of the current political, economic and social situation in Ukraine. There is no doubt that the destiny of bioethical ideas and their practical implementation will depend on the nature, quality and rate of the democratic transformations in all spheres of Ukrainian society. The experience of the development of bioethics in Ukraine allows hope that humanistic and bioethical changes are irreversible, not only in people’s minds, but also in people’s lives. This experience gives us hope for our gradual advance towards more solid guarantees for our rights for life, for health and harmonious development.

Notes

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