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## **BIOMEDICAL INVESTIGATIONS IN THE CONTEXT OF INTERDISCIPLINARY STRATEGIES: MORAL AND LEGAL ARGUMENTS**

**Abstract:** The aims of this paper are: to show the dynamics of moral and legal arguments in the modern bioethics, to analyse retrospectively the main phases of the development of bioethics as a science, to find the developmental mechanisms of organizational and educational strategies of bioethical thinking and of the National Bioethical Committee in the Republic of Belarus. The paper also focuses also on particular aspects of cooperation between Ethics Committees (ECs) and patients in biomedical research.

**Keywords:** bioethics, legal arguments, evaluation of science, Chernobyl tragedy, cooperation between EC and patients.

### **1. Introduction**

The introduction of new medical technologies (methods of artificial impregnation, surrogate motherhood, prenatal diagnostics) into practice, the actualization of problems of transplantation, euthanasia, biomedical experiments involving human beings and animals, the necessity of moral, ethic and legal regulation of collisions arising in the process of biomedical investigations served as specific social demands for the formation of bioethics as an interdisciplinary area of scientific research.

The interdisciplinary strategies represent the organization method of research activities provided for the interaction in studying one and the same class of objects and systems by the representatives of different scientific disciplines.

Moreover, the modern scientific knowledge forms the transdisciplinary strategies thus ensuring an innovation system of the scientific knowledge organization. The system isn't limited with the interdisciplinary ties only, but it comes to the necessity of involving the social values and standards in the humanitarian examination of the modern scientific projects and their correlation both with the interscientific ideals, standards and values and with the social and humanistic priorities and requirements.

The evaluation of science and technique becomes a variety of social and organizational development of the system and a dialogue of science, technique, policy, ethics and civil society. It becomes impossible to supervise the rapidly rising changes in the ambient environment caused by the unregulated scientific, technical and industrial development.

A new understanding of scientific rationality appears that goes beyond the scope of disciplinary rationality and includes the political, social, humanitarian, philosophical aspects and the system of values as well as the ethical attitude to science and technique since the power and knowledge causes a specific responsibility – the responsibility of a competent and ruling person. Being a specific social institution, the modern science generates the standards of moral regulation and proves not a humanistic vector of its modern development only, but orientates other phenomena also on high ideals of cooperation, co-creativity, intransigence, synthesis of truth and morality, dialogue of natural, technical and humanitarian knowledge. A specific role here plays such an interdisciplinary science as bioethics (Yaskievich 2008).

## **2. Bioethics as an interdisciplinary science: its brief history, status and role**

Bioethics as an interdisciplinary scientific trend becomes outlined in the context of common stylistics typical for the post-nonclassical science of the last third of the XX century as a whole when it becomes enriched with such unusual for classical science ideals and arguments as well-being of a man and mankind, good and morals, duty and responsibility for the results achieved in the process of scientific investigation of human objects.

The thirty years period of existence of this interdisciplinary trend combining biological knowledge and human values and representing a “systematic investigation of human’s behavior in the field of sciences of life and health care so far as the behavior is considered in the context of moral values and principles” (*Encyclopedia of Bioethics* 1995, p. 102) was connected with the dynamics of bioethical problems ranging from the empirical arguments and descriptions of doctor’s moral to the philosophical introspection of morals in the area of biomedical study. Starting from the second half of the 80-th, quite a powerful layer of philosophical knowledge transforming the conceptual foundations of a traditional model of the Western type of bioethics was formed alongside with the development of biomedical technologies. The problems of personal rights and liberties typical for bioethics were actualized in a new way; a wider understanding of the term

“freedom” was formed including the recognition of personal autonomy. In the framework of contemporary interpretation of personal autonomy it is regarded as the basic ethic value manifested as a patient’s free choice of either medically possible or medically human. More profound ethics of dialogue combined with the principle of informed consent replaces the ethics of paternalism that dominated in traditional model of bioethics. Instead of priority absolutization of both the doctor or biologist (experimenter) and the patient (or probationer), the modern model of bioethics prefers the argument structures aimed at coordination in grounding the rights and duties of the sides, the active attraction of patients to make decisions in choosing the treatment methods especially in case of risk for the person’s life.

As far as our knowledge of living matter becomes more extensive, the main philosophical accent in considering the category of freedom is shifted from the *consumer’s freedom* (“freedom from”) to the *creative freedom* (“freedom for”). At the same time, the “freedom from” is interpreted as the present-day person ability to overcome natural forms of dependency on the outer world and to satisfy his growing demands (prolongation of active life period including even life maintenance at a vegetable state, treating the illnesses that were incurable before, freedom in changing the appearance and/or gender, personal choice to have or not to have children even without a man, etc.). The modern level of biochemical investigation makes it possible for a person to achieve certain level of argumentation (“freedom from”), but getting separated from the nature and towering above the world the person sometimes becomes more and more dependant on the modern technique and only the natural unity of a person and the Space, self creation and moral self improvement makes a person closer to creative freedom of argumentation (“freedom for himself”). The value status of freedom in the development process of our knowledge of the alive nature, in performing biomedical investigations dealing with the unique isolated objects (human genome, social and natural systems) supposes the necessity of self-restriction from the side of researchers and the formation of argumentational concept of collective responsibility for the scientific study results as well as for the mankind unity. The concept of responsibility turns from an individual argumentation into a rank of collective responsibility argumentation for prejudice caused to people and nature.

Within the frames of bioethical argumentative discourse where morals appears traditionally in its highest sense due to its affect on inter-personal relations (doctor – patient, investigator – probationer) at boundary situations (on the verge of life and death, health and illness), the categories of justice, duty and humanism are philosophically revised. It becomes clear,

that a humanistic paradigm in bioethics can be implemented not only in case of observance of moral arguments and principles but in case of strict adherence to legal arguments and standards too. The concept of justice supposes the presence of social component and corresponding equal access to common wealth and availability of pharmacological means required for health maintenance.

The traditional bioethical arguments and categories of duty and welfare that were expressed in the Hippocrates' formula "don't make harm" (i.e. use only the medicines that make no harm to patient) were extended in the modern bioethics by transforming the above formula into "not only make no harm, but make good" although the interpretation of good deed concept is not monosemantic especially in discussing the problems of life maintenance at a vegetable level, cloning of living creatures and even a human being, etc.

The above paradigm appears in the Western model of bioethics as an institutionally organized social technology with the system of standard liberal values providing the observance of personal rights and freedoms in the biomedical area. The protection of civil rights against the negative consequences of modern biomedical technique usage (the main target of bioethics) is implemented by using ethical and legal arguments, developed ethical codes, laws and by increasing the area of responsibility of doctors and biologists as well as by extending their social duties fixed not only at personal but at legal level too. The ethical control mechanisms of doctors and scientists activities are added with the developed system of legal supervision, foundation of special bioethical committees, and formation of bioethical education (Sheets, ed., 1986).

The post soviet area including the Republic of Belarus is characteristic for its own ("domestic") model of bioethics which considers bioethics as an interdisciplinary and biologically oriented area of modern knowledge analyzing the moral problems of human being existence and his attitude to life and to certain living organisms. The development of mainly moral arguments and principles regulating practical activities of people in the study of nature and human being, the moral criteria of social activity aimed at the environment transformation, the evaluation of role and place of a person within the frames of biological reality, theoretical grounds of co-evolution concept of nature and society, the category status of life and death – such is the range of the domestic model of bioethics based on the extended interpretation of its problem area and subject. It is evident that at present we can't develop bioethics in the way accepted in the West with its developed system of legal regulation due to the insufficient propagation of scientific knowledge both among the medical professionals and the population, poor

juridical education of people and insufficient availability of equipment for biomedical study.

The priority trend of bioethics is the development of ethical and legal arguments and the analysis of ethical standards of health care taking into consideration the social essence and the main principles of organization and functioning of a human being as a bioethical system. The human being health steps forward as the leading indicator of a complex co-evolutional development of the nature-human being systems. Here we can speak of the coincidence of goals of bioethics and ecological ethics in the context of ensuring ecological safety and health of population under the conditions of environment contamination and changed balance of “human being-Nature” system.

### **3. Bioethics in the light of Chernobyl tragedy**

The status of bioethical arguments and criteria in the Republic of Belarus at present has a special significance due to the crisis state of balance in the system of “human being-Nature”. The results of biomedical investigations show the direct and implicit threat to population health and to gene pool safety owing to complex radioactive and chemical pollution of Belarusian territory. The Chernobyl catastrophe (April, 1986) played especially negative role in this process as the greatest man-caused tragedy in the history of mankind. Namely this catastrophe caused especially great damage to the Republic of Belarus and showed that such catastrophes ignored boundaries and that the world was in the greatest ecological integrity thus reminding the topicality of V. Vernadsky’s idea of the integrity both in planetary and Universe aspects.

The biomedical and the ecological health control of population residing within the contaminated areas of Belarus shows the threatening dynamics of illnesses growth among the adults and children in particular. It also indicates that the areas are contaminated not only with radionuclides, but with chemical substances too. As a whole, all this brings a long-term post-catastrophe emotional and psychological stress, feeling of mutual anxiety that arouses and lasts for a long time among the population of not only contaminated territories, but also of the whole country. Only 18 per cent of children grown up during the last years are completely normal from the medical point of view. The most spread illnesses are: cancer (thyroid cancer), respiratory diseases, stomach-and-bowel diseases, and cardiovascular diseases. Unfortunately, clinical practice shows that thyroid cancer in case of children is more aggressive than in case of adults and that children with ablation of gland

are slow in most cases in their intellectual and physical growth compared to other children of their age. At the same time, the growth of cases of such diseases as flue and cataract takes place in kindergartens and health index of pre-school children comes down.

A lack of medical and sport equipment for health recovery aggravates the problem of ill people treatment. The complex prophylactic and sanitary measures in children pre-school and polyclinic institutions, biomedical intervention for studying persons residing within the environmentally unfavorable areas must be the supreme line in this situation. It should be noted that the intervention is to be carried out with the agreement of informed adult or with permission of parents (tutors) in case of children under sixteen. The realization of supposed biomedical scientific study with the intervention into psychophysical state of people (blood sampling, echography, etc.) must have the scientific and practical validity and the assessment of potential risk and benefit. The studied persons must be guaranteed with confidentiality of the information obtained. The modern interdisciplinary environmental investigations should attract specialists of different sciences – biology, medicine, ecology, sociology, demography, ethics and philosophy. Bioethics from this point of view can significantly contribute to the evaluation of environment, dynamics and prophylaxis of population health. The continuous biomedical and ecological control for the health of population residing within the contaminated territory of Belarus and the resettlement of people into the “clean” areas gives the positive results undoubtedly.

#### **4. The legal and educational basis of biomedical investigations: international and Belarusian experience**

Like in the area of both the health care and the formation of local and national ethical committees, the Republic of Belarus follows the international legal and ethical standards first of all. They are: *Nuremberg Lawbook*, 1947; *Helsinki Accord on Human Rights* (with add-ins), 1964; ICH GCP, 1966; *Recommendations on Ethics to Committees Controlling Bioethical Researches*, WHO, 2000 and such UNESCO documents as *Declaration of Tolerance Principles*, 1995; *Universal Declaration on Human Genome and Human Rights*, 1997; *Universal Declaration on Bioethics and Human Rights*, 2005; UNESCO Instruction 1 on the *Formation of Bioethical Committees*, 2005; UNESCO Instruction 2 *Activities of Bioethical Committees: Rules, Procedures and Political Principles*, 2005.

The Republic has *National Strategy of a Steady Development* and *The Concept of Health Care Development in the Republic of Belarus*, 1995. They

form the basis for the approval of legal acts and national programs defining the specific actions and the sources for the ethical and legal control of biomedical researches. The main principles of bioethics recommended by WHO are fixed in the laws of the Republic of Belarus *On Health Care* (1999 with the further add-ins); *On Safety of Gene and Engineering Activities*, 2005; *On Transplantation of Human Organs and Tissues* and in a number of orders and instructions of the Ministry of Health Care.

Alongside with the formation of legal status of bioethics, its social and ethical arguments and grounds are developed with the use of Christian morality too. The Moscow Eparchy already has the acting Public Church Council on Medical Ethics and the same fund is planned to establish in Belarus. Christianity holds a very stiff line on some bioethical problems: cloning of a human being and his (her) organs (heart in particular), euthanasia, artificial conception and abortion which are considered as an encroachment on life of a future individual. Cloning of separate cells and living tissues of organism, gene-therapy, transplantation of separate organs, study and usage of a number of modern molecular and genetic methods of treatment is considered applicable and useful. A woman aborted pregnancy due to the direct threat to her physical and mental health is not excommunicated, but she has to read special personal repentance penitence established by the priest after confession. The Minsk Eparchy of Belarusian Exarchate has accumulated a significant experience in spreading of bioethical ideas by the Orthodox Congregation of Doctors and a house of charity has been built at the parish of All Saints in Minsk. The spiritual medico-psychological assistance to the hopeless case children is rendered at the Belarusian Children's Hospice at the oncological centre. Thus, bioethics as a social and cultural phenomenon of our society determines in many respects the cooperation and mutual enrichment of argumentation of legal and moral senses and sets the guiding line of biomedical practice and acceptance of management decisions. All this provides the required moral climate in scientific community, medical collectives and adequate moral choices for doctors, biologists, biotechnologists, their intervention into the sphere of living matter, social and legal responsibility for the results of scientific and practical activities.

When the mutual influence of ethical and scientific discourse in the science as a whole and in bioethics in particular is very limited for the "domestic" model of bioethics since its core problematic is mainly the development of moral arguments and principles regulating human behavior in sciences of life, human being, animate nature (bios), the formation of legal argumentational status of bioethics is still in progress. And though A. Puanicare at the beginning of the XX century said that any juridical in-

interference into the problems of scientific investigation would be mistaken and incongruous, many scientists at the end of XX – beginning of XXI century began to appeal to scientific tribunal for adjusting the arbitrary scientific problems and elaborating the code of laws for scientific investigations. Bioethical knowledge fulfils successfully different functions in the process of its development including ideological, gnoseological, methodological, axiological ones promoting the development of system of arguments, values, goals and ideals concerning the assessment of life state and its development prospects, moral and legal standards of investigations in biomedical study and technique, modern tendencies of functioning of scientific knowledge of living systems, dialogue and mutual enrichment of scientific and humanitarian discourse, interdisciplinary synthesis as well as the improvement of ideological and ethic health of society.

This dynamics is proved to be true by the international scientific conferences (*Ecological Problems of the XX Century* of 1999, 2000, 2001; *Strategy of Steady Development and Prospects of Civilized Dynamics at the Turn of Centuries* of 1999–2003; *Biomedical Ethics: Problems and Prospects* of 2000–2005), the participants of which were scientists, lecturers, doctors, ecologists, clergymen and others. The curriculums of institutes of higher education of our country were added with such courses as *Biomedical Ethics*, *Ethics of Ecology*, *Bioethics*, *Concept of Modern Natural Science*.

The international seminar *National Bioethical Committee of the Republic of Belarus and Activities of Local Ethical Committees* was carried out in Minsk on June 6 to 8, 2006. The National Coordinating Centre on Biosafety has been established in 1998 at the National Academy of Sciences.

The National Belarusian Bioethical Committee was formed on April 2006. The author of this paper is its present vice-chairman. Taking into account a world-wide experience, the formation of Bioethical Committee in the Republic of Belarus was preceded with the basic organizing, scientific and educational activities in the light of national, social, cultural, historical and political traditions. Like the Danish Council on Ethics and the Czech Ethical Committee, the Belarusian National Bioethical Committee was formed at the Ministry of Health with the help of Belarusian National Committee on UNESCO affairs.

In general, Bioethical Committee is at present the most important structure for observing various legal acts accepted by UNESCO – the leading international organization in the area of bioethics. The National Belarusian Bioethical Committee is destined to provide all possible assistance for strengthening the confidence, consolidation and partner relationships between the doctors (and other medical workers) and the patients reaching

the consent by means of objective and principal discussion of situations being complex in moral and legal aspects. The Ethical Committees (ECs) examine all the questions dealing with observing general principles of humanism, morality and biomedical ethics.

## **5. Ethical and legal parameters of cooperation between the ECs and patients**

The state policy in health care, legal, economic and ethical issues regarding biomedical investigations of human subjects, as well as patient rights and responsibilities are defined in the *Law on Healthcare of the Republic of Belarus* (1993). According to Article 31 (*Conducting Clinical and Biomedical Research Involving Human Subjects*), clinical and biomedical studies of human subjects for therapeutic purpose should be carried out in the state healthcare institutions. The studies should be scientifically justifiable and performed under a freely given written consent of a studied subject to participate in the investigation based upon the explanation of all relevant information (research goals, duration, anticipated results and possible consequences for research participant's health). Clinical and biomedical investigation of pregnant women and minors is unacceptable, with the exception of cases when the research is performed for the diagnostics and treatment aims in this particular contingent. The study of children should be necessarily based on the written consent of one of the parents. It is not permitted to carry out clinical and biomedical investigations of neglected children without parents' charge, servicemen, convicted prisoners, persons under arrest, mentally incapable persons (with mental disorders), those incompetent according to law, persons compulsorily hospitalized or receiving compulsory treatment at psychiatric hospital.

The rules of medical ethics and deontology reflecting the basic principles of biomedical activity and patient–doctor relationships are defined in the *Code of Medical Ethics* adopted at the First Congress of Belarusian Physicians (1998) and approved by the Ministry of Health of Belarus (1999). Part III *Physician-Patient Relationships of the Code* states:

- Asset 14. Physician and patient have equal rights to respect for human dignity and can protect those in accordance with the current legislation.
- Asset 15. Rude and inhumane attitude, dishonor or preferential attitude in physician's work is absolutely unacceptable.
- Asset 16. Patient-physician relationship should be based on mutual trust and mutual responsibility. Patient is an active participant in the process of treatment.

- Asset 21. All medical interventions should be performed with the patient's consent only for the exception of particular cases when the patient mental status doesn't allow making a reasonable decision due to his severe condition or in other cases defined by law.
- Asset 23. Organs and tissues for diagnostic or treatment purposes can be taken with the patient's written consent only as stated by law or with consents of patient's close relatives or legal representatives as specified in some cases by law. It is prohibited to take patient's organs and tissues for any other purpose.
- Asset 24. The physician should follow the rule of confidentiality with regard to his relationship with the patient and must not disclose patient's confidential information even after patient's death. Physician should also prevent others from disclosing confidential information.

When performing the studies of human subjects, Ethical Committees established at medical-prophylactic institutions and medical universities of Belarus complies to international guidelines defined in *Helsinki Declaration: Ethical Principles for Research Involving Human Subjects* (Helsinki, 1964); *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva, 1993); *Lisbon Declaration of Human Rights* (Lisbon, 1981), et al.

To control the work of ECs, the Ministry of Health of Belarus developed Methodical Recommendations “*On the Order of Establishing and Performance of Ethics Committees*” (2000). The Recommendations cover the problems of organization and performance of EC in compliance with the WHO Project *Implementation of International Standards into the Practice of Clinical Trials in New Independent States* (Geneva – Moscow, February 1999). They define the formation mechanisms of EC and its authorities. EC must monitor the observance of *Rules of Conducting Clinical Trials of Pharmaceutical Products*. The main goal of EC is to provide protection of safety and health of all studied subjects. In order to reach this goal, EC should:

- inform investigators about all ethical and procedural problems regarding human subjects involved in the research, assist them in solving all problems associated with the research and provide its compliance with the requirements stated in regulations;
- assist researchers in planning their projects for minimizing potential harm for the subjects under study, review all project materials prior to start the research and approve only those of them that meet all requirements for the study subject protection;

- monitor the course of the approved research for providing the real protection of the study subjects.

Rights, safety and health of the study subjects are absolutely essential and should prevail over the interests of science and community. To protect the study subject interests, EC should consider all issues relating to the information presented to the subjects under study, investigator's experience, confidentiality and payment for studying subjects (if stipulated).

All issues connected with the EC composition should be considered in line with the following *basic principles*:

- EC members should be competent and reasonable enough to review ethical aspects of a clinical trial and decide about their adequacy to international ethical principles.
- When making decision, EC should take into account the opinions of the society representatives (i.e. non-medical persons).
- EC members should work on a voluntary basis, with a due respect for human personality and welcome scientific progress in the interests of all mankind.
- The number of EC members should be no less than 5, and not more than 12; they should be no younger than 21, and include both men and women.
- The term of membership should be 5 years with a possible prolongation for another 5 years if the member meets all necessary qualification requirements.
- The chairman is elected by EC members at the EC meeting; EC chairperson should have a higher medical education, possess expertise in ethical issues and knowledge of regulations for performing clinical studies; the vice-chairman and the secretary are also elected at the EC meeting.

When analyzing the risk to benefit ratio, EC should make sure that information submitted by the investigator is sufficient for the valid conclusion about the risk and the benefit for the study subjects; determine the level of the treatment risk for the patient associated with the given study in comparison to that when the patient doesn't participate in such study; to make sure that the risks for subjects in study will be minimized and the potential benefits for the studied subjects will be found.

When analyzing the recruitment procedures of the study subjects, EC should confirm that the choice made was fair and unbiased. If the subjects from the vulnerable groups are involved into the study, their participations should be adequately justified and additional guaranties for protecting their health and rights must be provided.

EC should consider the order and the amount of payments for the study subjects to make sure that there is no undue interest or pressure. EC should also analyze all information regarding the payment for studied subjects (if stipulated). Methods, amounts and order of the payment are described in details in the form of written informed consent.

EC meeting discussing ethical aspects of clinical trial should end up with a decision making. The following *decision versions* are possible:

- approval of the study;
- requirements for making changes or amendments into the submitted documents in order to obtain the approval;
- refusal.

Thus, EC as an independent body functioning within the medical and prophylactic institutions, in health care authorities and medical universities of the Republic of Belarus fulfills its main tasks and functions in the sphere of rights and health protection of the study subjects. Together with other health institutions in Belarus, EC provides the ethical and the legal basis of cooperation with patients.

## **6. Theoretical and methodological principles of cooperation between EC and patients**

ECs perform their functions basing on the following *principles*:

- Biomedical study of human subjects should be performed in line with commonly accepted *scientific principles* and based on the cutting edge scientific data, adequate scientific results of laboratory investigations including the study of animals.
- Goals and objectives of each investigation of human subjects should be clearly defined in the research protocol (RP) submitted to EC for examination.
- Biomedical study of human subjects should be carried out only by the experienced specialists supervised by a competent physician with a sufficient clinical experience. *The responsibility for the subject in study rests always on physician*, and by no means on the subject even if it is the subject's agreement.
- Each clinical trial should be preceded by the thorough evaluation of *a probable risk and potential benefit*.
- Biomedical study of human subject must not be conducted if a possible risk prevails over the expected benefit. A physician should avoid such investigations till he is sure that a possible harm can be predicted. *The*

*interests of the subjects in study should prevail over the interests of science and society.*

- Measures should be taken for safeguarding the respect of the *study subject personality* and for reducing the adverse effects on his expected benefit physical and mental abilities.
- *When publishing the results of the study, the physician should check them for accuracy.* The papers based on the experiments carried out without the observance of principles of the Declaration must not be accepted for publication.
- Each potential participant of a study should be adequately informed about the research goals, methods, expected results and potential risks or dangers, as well as about the possible discomfort associated with the research. *The study subjects should be duly informed about their rights to refuse participation in the study and to exit it at any moment.* The physician should obtain the written free informed consent of a subject for his participation in the experiment.
- In case of the study subject inability, the informed consent should be obtained *from his legal representatives according to the national legislation.*
- RP should always contain statements related the ethical aspects proving the observance of the Declaration principles.

When performing a purely scientific medical investigation of a human subject, EC should make sure that the physician provides due protection of life and health of the subject under study. Mainly the healthy volunteers should be involved into the study or when the patients are studied, their diseases should have no relation to the investigation. The investigator should suspend the research if he sees that its continuation can be harmful for the studied subject.

The cooperation between EC and patients is based on the ethics of patient–doctor relationship. R. Veatch, an American specialist in medical ethics, mentions 4 types of the relationship models:

1. *The engineering model.* According to this model, health care professionals behave as applied scientists. It means that the scientist should be “unbiased”, based on facts only and stay value-neutral. This model turns a physician into a plumber who clears blocked pipe systems and connects them without setting himself on any moral issues.

2. *The sacral model.* Another extreme, when a physician turns into a priest giving more for patient’s soul than for his body. The main moral principle representing this tradition is: “make no harm when treating a patient”.

3. *The collegial model* suggests that a physician and a patient should be colleagues pursuing a common goal – to treat the disease and to protect the patient's health. A mutual trust is absolutely required for this model.

4. *The contractual model* is based on contract or agreement. It does not mean signing a judicial document. This model of the relationship between the patient and the medical professional attempts to capture the desirable features of the above models. It implies a true sharing and each party has its own role in the process of decision-making. The relations based on a contract or informed consent ultimately allow patients to make final decisions. They give the priority to the person autonomy as well as to his needs and values. When searching for the most optimal type of relations between the medical professionals and the patients (to overcome problems arising in the course of treatment and to give hope and assurance to the patient in a beneficial outcome for his health), the former developed two main models of relationship – *the paternalistic model and the autonomous one*.

Historically, the paternalistic (from lat. 'pater' – the father) model of the patient-physician relationship implies that the physician (due to the constrained patient autonomy) is responsible not only for his actions, but also for the decision, which he made. The extreme forms of paternalism deprived a patient of his rights for choosing a physician or for participating in the decision making on the treatment strategy and methods. The model does not take into account the individual character of the patient, his activity and free will. Therefore, it was necessary to develop a more adequate model based on the *democratic values such as solidarity, compassion and idea of communicational interests* (B. Jennings). A more considerate ethical approach is gradually supplanting the paternalistic model that was standard earlier.

The current model of biomedical ethics implies the prevention of absolutism both on the part of a medical professional and a patient. Instead, it offers cooperation and consensus with regard to the rights and responsibilities of both parties and to the active participation of a patient in decision making in case of risk to his life and health. This model is undoubtedly more adequate to the bioethical problems that must be solved (euthanasia, transplantation, new reproductive technologies, etc.).

This is the reason for implementing (in line with the WHO recommendations) a new *autonomous* model of the patient-physician relationship. This model is based on the principle of patient autonomy and implies that the medic should take into account the patient's opinion and be more precise in making decision. While the paternalistic relation type means that the information given to the patient depends entirely on the physician's free will

and wish, the autonomous model implies that the physician must provide the patient with the adequate information, and the patient has rights to receive information on all existing methods of treating his disease and on risks associated with each method of treatment. It is clear that the right of choice does not entirely belong to the physician, but is shared with the patient.

The ethical principles of the new approach respect *the autonomy and benefit of a person*. The reasonable decision made in the process of information collection is based on a mutual respect and an active cooperation. The medic should take into account the following moments:

- *patient's competence* that depends on a number of factors ranging from his general cultural level to his psycho-emotional state;
- *patient's awareness* implying his right to know the whole truth about the level of his health and on the methods of treatment;
- *free decision-making* that sometimes is a formal act, i.e. the patient signs a form of informed consent which warns that otherwise they will not obtain an adequate medical care.

Legally, the *model of patient's autonomy* with its rule of *informed consent* is fixed in the "Law on Healthcare in the Republic of Belarus". The Asset 27 of the Law states, in particular, that a patient's free informed consent should be obtained prior to a medical intervention. Every patient has the right to choose a physician (Asset 29). A clinical and biomedical research can be performed only if the written consent of a person to participate in the study is obtained (Asset 31), etc.

The autonomous model substitutes gradually the model of paternalistic relations. It incorporates the principle of informed consent; the observance of patient's rights including the right for truthful information on his health level, methods of treatment, the information on alternative treatment methods and possible risks. A physician should skillfully involve a patient in a dialogue and guide him along the way of decision-making. Thus, the model suggests an equal partnership in the physician-patient dialogue and increases the patient's responsibility in making the decision about the treatment, disease prevention and medical rehabilitation.

The information on the level of health and a medical prognosis allows the patient to actualize his right to make decisions related to his life. The patient may wish to complete some work or to solve certain problems with relatives, friends, illegitimate children (if any) or to disclose some important information to the law-enforcement agencies, etc.

In 1994 WHO formulated three basic components of relations between physicians and patients (everybody's right to health, patient's right to in-

formation, physician's responsibility to answer all patient's questions) and approved officially the principle of providing a patient with the reliable and understandable information prior to start of the treatment. In order to give adequate and reasonable answers, *a physician in his turn should have the access to the objective and controllable information.*

There is no doubt that the model of patient's autonomy is more efficient than the paternalistic model, but it may be successful only if medics observe their professional code, publish documents on patient's rights and create the atmosphere facilitating the therapeutic dialogue.

With all positive features of the autonomous model, we often face situations that force a physician to act without the patient's consent. Firstly, this is a situation when the patient's condition does not allow him to participate in making decision on a medical intervention (a surgical patient in the unconscious state). Here, the paternalistic model is absolutely justifiable and applicable. Secondly, there are situations when the decreased level of psychic and intellectual abilities (e.g. alcohol or drug intoxication or mental disorder) may become the decisive factors in choosing the model of relationship. Such situations cause problems with regard to using the autonomous model.

Perhaps, in case of reduced level of the patient's autonomy it would be reasonable to introduce a border-line model of the *soft paternalism* including a partial limitation of a person's autonomy when it is necessary to prevent a person against his self-damnation (suicidal attempts, drug hallucinations, etc.) and to observe him within a certain period.

The effective mechanisms of cooperation between ECs and patients participating in a biomedical study are provided with the physician (investigator) craft:

- compassion;
- high professionalism;
- courage;
- law compliance;
- adherence to principles;
- ability to mutual understanding;
- dignity;
- strength of will;
- commitment.

The current level of medical investigations should not be reduced to the analytical study of a separate phenomenon only without taking into account its connection to a more complicated dynamic system. The holistic approach implies the understanding of a disease as an inner dynamic system. Its

performance depends on a wide range of factors – from genetic to social ones. It is important to study a human organism within the frames of a treatment process. The patient is not a mere object of diagnostics, but a subject with a complex psychic world and individual responses to diseases or conditions of microsocial environment.

When the physician concentrates his attention only on symptoms of a pathological process, the patient is treated as a carrier of certain symptoms and his individual emotional response may affect the course of the disease and the therapy may be ignored.

## **7. Ethical problems of genetic testing**

One of the most essential aspects of EC activity nowadays relates to ethical problems associated with the genetic studies. “Universal Declaration on Human Genome and Human Rights” was adopted by acclamation at the 29th Session of UNESCO General Assembly on November 11, 1997. An evident strong point of this document is the achieved balance between safeguarding the basic human rights and freedoms and the necessity of providing the opportunities for the study performance. The Declaration was accompanied with the resolution stating that the member States are responsible for taking relevant measures facilitating the implementation of the Declaration principles. The Declaration marked the beginning of a new stage on the way of thinking about the ethics of science and technique.

The last decades of the XX century were marked with the rapid development of one of the most important branches of biological science – molecular genetics that stimulated the development of a new field – genetic engineering. The latter gave start to development of different biotechnologies producing genetically modified organisms (GMO) and genetically modified products (GMP). There are opportunities for genetic therapy of some human diseases, embryo and somatic cells, creating identical genetic copies of an organism and other relevant directions. These forms of genetic intervention into the nature of an organism require evaluation and discussion of social and economic consequences just now. Decisions resulting from the discussions influence the directions and investigation themes and help to form an adequate society response regarding the necessity and justifiableness of genetic investigation.

It is quite obvious that genetic and biotechnique have a tremendous potential and possibility for effecting human beings and society. However, the prospects are double-natured. Thus, in spite of all scientific and econo-

mic benefits of genetic engineering, it is necessary to evaluate its potential dangers for human beings and humanity in particular, the dangers that may be caused with the further intervention of human intellect into the Nature.

If everything that genetic engineering can do with microorganisms and separate cells can, in principle, be done with a human being too then the prospects of introducing the intentional changes into the hereditary material may be extended from reproduction of a genetically programmed individual or clones to creation of chimeras (a human being combined with an animal). A human being becomes an object for genetic technologies. We should remember also that some scientists believe that their activities mustn't have any limitation: they may do everything they want to do. However, when the reconstruction of an adult person genome is ethically and medically acceptable, the changes introduced into the genome of embryo cells present an entirely different situation.

By the beginning of the XXI century the investigations in the area of genetic engineering become more and more affecting the society interests and ethical problems compose a significant part of activity of specialists in biology and biomedicine. Nowadays a world community and scientists are actively discussing harms and benefits resulted from the achievements of genetic engineering. More and more scientists agree that studies in the area of genetic engineering should go on, but they should be focused on treating diseases but not on improvement of the human being nature. *The Universal Declaration on Human Genome and Human Rights* states: "The aim of the applied use of results obtained during the scientific study of a human genome (particularly in biology, medicine and genetics) should be the relief of human sufferings and improvement of health of both an individual and all people as a whole".

The last decade of the XX century was marked by another significant event – a tremendous progress was achieved in *cloning animals from somatic cells*.

The methods of animal cloning are still far from being perfect. The experiments showed a high mortality rate of fetus and newborns. Many theoretical issues on cloning animals from the somatic cells are still not clear. Nevertheless, the achieved success showed a theoretical capacity for creating *genetic copies of human beings* from an isolated cell taken from any human organ. Many scientists are very enthusiastic about this prospect.

At the same time, Asset 11 of the Declaration states that the practice conflicting with a human dignity (particularly the practice of cloning with the purpose of reproducing individuals) should be prohibited. The Council of Europe also introduced an amendment into the *European Convention on*

*Human Rights and Biomedicine* that outlines: “To forbid any intervention pursuing the goal of creating a human individual identical to another one – both alive and dead”.

Anyway, the task of biomedical ethics is not to forbid or to impose a moratorium on new and old biotechnique, but to facilitate their development and moral use. To forbid, for example, any manipulations with embryo would mean not only the development termination of methods of extracorporal fertilization allowing some women to conceive a child in a natural way; it would also mean the closure of an entire scientific field of embryology that helps to study many severe diseases and look for the ways of treating them. The prohibition of human being and animal cloning and the creation of transgenic animals would mean not the development termination of an entire scientific direction only but that in the future we should purchase the products of scientific achievements of the leading world companies.

The current level of genetics allows us to pose a problem of ethical justification of intervention into biologic processes responsible for the reproduction of human generations. The following problems are essential:

- detection of carriers of hereditary diseases;
- prenatal diagnostics and selective abortions;
- entirely new ways of overcoming the problem of sterility including outer intervention into the reproductive functions of human organism.

In any case, from the moral point of view some studies of fetus should be forbidden. Embryos exposed to any effects must not be implanted into a female organism. Human embryos must not be implanted into an animal organism. An illegal sale and purchase of embryos is also unacceptable.

We should also bear in mind that the studies of embryos may be very beneficial for the society since they facilitate scientific studies in different fields of medicine and biology. It may facilitate the development of new methods of contraception, the solution of sterility problem, the detection of hereditary fetus diseases, the study of mechanisms causing spontaneous abortions and processes of egg cell development, the study of cancer genesis and the search for the development regularities of a human being as a biologic specie.

Thus, *the modern paradigm of bioethics is characteristic for the radical turn from the arguments of empirical description of medical morals to the thorough philosophic argumentation – the revision of grounds of morals in medical studies, concepts of moral values, widening of problem area of bioethics by enriching it with moral, philosophical, legal arguments and components as well as integration of different arguments and kinds of values: biological (physical existence, health, freedom of pain, etc.), social (equal*

Yadviga Yaskevich

opportunities, availability of all medicines and medical services, etc.), ecological (understanding of the Nature self-value, its originality, co-evolution), personal (safety, self-esteem, etc.).

As a whole, the modern argumentative model of bioethics and the development of programs of biomedical investigations in the Republic of Belarus are adapted to the scientific, social, cultural and ideological traditions, to its system of public health care and needs further development.

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