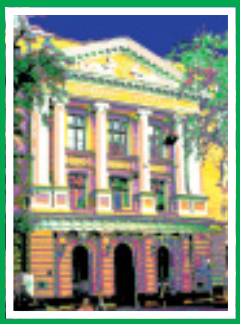

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BIOETHICS

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Medical Student's Library

Initiated in 1999 to mark the Centenary of the Odessa State Medical University (1900 — 2000)

Edited and Published by V. M. Zaporozhan, the State Prize-Winner of Ukraine, Academician of the Academy of Medical Sciences of Ukraine

The Odessa State Medical University

Dear Reader,

When in 1999 the lecturers and researchers of the Odessa State Medical University started issuing a series of books united by the collection entitled "Medical Student's Library" they had several aims before them.

Firstly, they wanted to add new books to the Ukrainian library of medical literature that would be written in Ukrainian, the native language of the country. These books should contain both classical information on medicine and the latest information on the state of the art, as well as reflect extensive experience of our best professionals. Secondly, our lecturers and specialists wanted to write such books which reflected the newest subjects and courses that have recently been introduced into the curricula, and in general there have been no textbooks on these subjects and courses at that time.

These two aims have successfully been coped with. Some dozens of textbooks and workbooks published in these years have become a good contribution of their authors and publishers to the development and making of the Ukrainian national educational literature.

The next step that we decided to undertake was to issue a unique series of books in foreign languages. The foreign students taking their medical education in the Ukraine, our University included, are expecting such books to be published. Other countries are also waiting for them as the Odessa State Medical University is a Fellow Member of the International and European Association of Universities. Our Medical University is over a hundred years old and has long since become a center of various original medical schools and trends. These are headed by well-know medical professionals whose competence is acknowledged not only in this country, but abroad as well.

Valery ZAPOROZHAN,
Editor-in-Chief of the Series "Medical Student's Library"
the State Prize-Winner of Ukraine,
Academician of the Academy of Medical Sciences of Ukraine

V. M. Zaporozhan
M. L. Aryayev

BIOETHICS

Recommended
by the Central Methodical Commettee
on Higher Medical Education of the Ministry
of Health of Ukraine as a textbook for the students of
higher medical educational institutions
of the IV level of accreditation

Odessa
The Odessa State Medical University
2008

ВВС 87.75я73
UDC 57:17

Authors: V. M. Zaporozhan,
M. L. Aryayev

Reviewers: Academician of the National Academy of Sciences of Ukraine, the Russian Academy of Medical Sciences, Academy of Medical Sciences of Ukraine, director of the Institute of Paediatrics, Obstetrics and Gynaecology of the Academy of Medical Sciences of Ukraine, professor O. M. Lukyanova

Corresponding member of the Academy of Medical Sciences of Ukraine, rector of the Kiev P. L. Shupik Medical Academy of Postgraduate Education, Yu. V. Voronenko

Translated from Ukrainian by O. Yu. Donets

This textbook contains information on the subject, theoretical bases and stages of development of bioethics as a discipline. Bioethical aspects of relationships between the medical personnel, a patient and his family members, issues of dying and death, reproduction of man, control of genetic technologies, medical research and social ethics of medicine are considered in this book.

The book is designed for students, teachers, and practical doctors of different specialities.

Рекомендовано Центральним методичним кабінетом з вищої медичної освіти МОЗ України як підручник для студентів вищих медичних навчальних закладів IV рівня акредитації Протокол № 1 від 12.04.2005 р.

ISBN 978-966-7733-47-6 (серія)
ISBN 5-311-01392-3 (ориг.)
ISBN 978-966-443-006-4

I believe, a day will come, when a patient with an unknown illness will give himself up to the hands of physicists. Asking no questions, these physicists will test his blood and show out some permanents. They will multiply the permanents, then collate the obtained figures with the table of logarithms, and cure him with one pill. However, if I will fall ill, I will go to some country doctor. He will glance at me from the corner of his eye, feel my pulse and stomach, listen to my lungs, then clear his throat, light his pipe, and rub his chin — he will smile at me, to appease my pain better. Certainly, I admire science, but I admire wisdom too.

Antuan de Sent Exupery

INTRODUCTION

"Science without conscience devastates the soul."

Fransua Rable

We have chosen as an epigraph to this introduction the slogan of the First and Second National Congresses on Bioethics, which took place in Kiev in 2001 and 2004. These to say the least epochal events are significant because they reflect the fact of formation and dynamic development of bioethics in our country, which has proclaimed its adherence to the principles of democratic construction of society and protection of human rights.

Bioethics became a logical answer to numerous ethical questions and problems which have appeared in the last decades in the process of clinical work, biomedical research and experiments. It is called not only to identify and analyse conflict situations at the junction of medicine, biology, philosophy and jurisprudence, but also to determine concrete ways of their solving.

The primary subjects of consideration of bioethics are the newest achievements in biology and medicine from the point of view of determining the level of their danger for man and society in the present and future. Bioethics is directed at the development of moral and legislative measures, which would shield an individual, society and humanity on the whole from undesirable and sometimes ruinous consequences of implementing new medical and biological technologies in practice.

The formation and striking progress of bioethics is related to revolutionary changes and achievements in the field of medical and biological disciplines. We speak about the decoding of the human genome, animal cloning, possibility of cloning of man, artificial change of gender, extracorporeal impregnation, using trans-genetic plants for food, success of gene therapy, treatment with the use of embryonic tissues, new methods of family planning, progress of transplantology, perfection of vaccine prophylaxis, introduction of the newest technologies of diagnostics, treatment and prophylaxis of different diseases of man. The issues of medical secret, euthanasia,

mother-foetus conflicts, family planning conceptions, and methodologies of biomedical research need new bioethical evaluation.

The development of bioethics was a direct result of the implementation of scientific and technical revolution achievements in practice in the situation of a deep ideological crisis and growth of global ecological problems. Enormous success of medical and biological sciences have generated a great number of questions of moral nature. The affairs amount to the situation, in which people try to spread their control over their own evolution and lay their claim not simply to supporting their life, but to improving and changing their nature, depending on their own understanding. In this situation grounded discussions concerning the ethical basis and moral competence of such actions arise.

Bioethics represents not only the modern stage of development of the medical ethics and deontology, but also a basis for establishing scientifically grounded balance between the newest medical and biological technologies on one hand, and human rights, principles of humanism and public progress — on the other. Bioethics is based on the respect of life and dignity of healthy and sick people, who's interests should always be estimated higher than the interests of science or society. The leading postulate of bioethics is the principle of autonomy with inviolability of human mental and physical status, which is realized according to the rule of informed consent of the patient and society to the execution of medical and prophylactic manipulations.

Bioethics unites a vast circle of socio-economic, moral, ethical and legal issues, which are considered not only by the medical community, but also by the state authorities, public, and mass media. Bioethical questions are discussed by the authoritative international organizations — UN, UNICEF, UNESCO, the European Council, and WHO. Appropriate declarations, conventions, agreements, recommendations, and resolutions of these organizations provide the development of national legal and ethical regulations of practical health services, medical and biological research.

During the last few years several steps were made in Ukraine on the way to the introduction of ethics principles in medical practice and biomedical science. In particular, a Commission on the Issues of Bioethics was created at the Cabinet of Ministers of Ukraine, Committees on Bioethics were formed by the National Academy of Sciences, the Academy of Medical Science and the Ministry of Health of Ukraine. Committees on medical ethics operate at the medical institutions, where clinical tests of new medicines and biomedical scientific research are carried out. In Lvov the Ya. Basilevich Institute of Bioethics was opened on the base of the Lvov branch of the President's Ukrainian Academy of State Administration and the Institute of Bioethics of the Rome A. Jameli University. The number of scientific publications on these issues grows continuously.

An important impulse for further development of bioethics in Ukraine was given by the conference of the European Council experts on the issues of biomedicine in Strasburg (France), in which a delegation from Ukraine took part. The participants discussed a complex of problems related to the European convention on the protection of human rights and dignity in connection with the practical use of biological and medical sciences achievements. One of the topics of discussion was the state of bioethics is Ukraine, prospects of ratification of the convention on biomedicine by the Supreme Council of Ukraine and further democratization of our domestic science. These issues become especially important at present — in the period of changes of the socio-economic relations in our country, and in particular, the reformation of the health services system.

Ukraine can and must make an important contribution to the development of bioethics. The geographical position of Ukraine, situated between the West and the East, undoubtedly, influences the forming of our philosophical views in science on the whole, and medicine and biology in particular. Historically our country has absorbed elements of Western technocratic science and Eastern spirituality. This harmonious unity, undoubtedly, promotes the humanization of medicine and the understanding of the human being as a unity of biological, psychological and social components. The collaboration of the Ukrainian higher medical educational institutions with foreign medical universities in administrative, scientific and educational regions promotes mutual penetration and enriching of the Western and Eastern cultures.

The authors had an opportunity to specify characteristic features of bioethical conceptions of the Western and East world views in the process of working on several partners programs, agreements and grants with higher educational institutions of the USA, Netherlands, Greece, Italy, Germany, Switzerland, Poland, India, Vietnam, Malaysia, China, and Syria.

While implementing international programs in the field of biomedical ethics, we clearly realized the value and role of national ethical traditions, as well as the existence of certain characteristic features of bioethical practice in multinational societies.

According to the WHO data, bioethics is one of the subjects currently taught in the majority of economically developed countries of the world. In Ukraine courses of bioethics are delivered only in some higher educational institutions, and there are not enough educational and methodological materials on this subject. There was an insistent necessity in preparing and publishing modern domestic textbooks, trains aids, monographs and informative materials on all the basic sections and issues of bioethics.

While preparing this textbook, the authors used their experience of practical work in the Commission on the Issues of Bioethics at the Cabinet of

Ministers of Ukraine, in the Committees on Bioethics of the Academy of Medical Science and the Ministry of Health of Ukraine, in the Committees on Medical Ethics at the base medical institutions of the Odessa State Medical University (OSMU) and took into account the results of the implementation of international scientific programs and projects on bioethics with leading foreign specialists — honoured doctors of the OSMU. Meetings and collaboration with outstanding specialists in medicine also helped us to understand modern progress trends in bioethics better. Among these prominent figures were professor K. Barnard (Cape Town University, Republic of South Africa), professor S. Marketos (the President of the International Hippocrates Foundation, laureate of the Olympic medal of Hippocrates), professor K. Imielinsky (the President of the International A. Schweitzer Medical Academy and the Polish Medical Academy, laureate of the Olympic medal of Hippocrates), the member of the Russian Academy of Medical Science, academician E. Chazov (the Director General of the Russian Cardiologic Research Complex, Nobel laureate, Russia), R. Ridgeway (the President of the International Association of Integrated Health care, Nobel laureate, Great Britain), professor B. Luban-Plotsa (the President of the Psychosomatic and Social Medicine Foundation, Switzerland), professor S. Trachtenberg (the President of G. Washington University, the USA), philosophy professor D. Bernardi (Turin University, Italy).

The authors got the newest information for this textbook in the process of their work as the members of the Council of the European Organization Of Psychosomatic And Social Medicine (Ascona, Switzerland), the International A. Schweitzer Medical Academy and the Polish Medical Academy (Poland).

The practical results of our international collaboration in the field of bioethics included our participation in the edition and publication in Ukraine of three books. They were: "50 Ways to the Healthy Heart" by professor K. Barnard (2001), "Albert Schweizer" by professor K. Imielinsky (2001), and a monograph "The Therapeutic Union of Doctor And Patient", written and edited in collaboration with professor B. Luban-Plotsa (2001). As a result, the authors were rewarded with the Olympic medals of Hippocrates.

The growth of public interest towards bioethics coincided with the reformation of the public health and higher education systems, and the development of a new conception of primary medical help in Ukraine. Today we have a unique possibility of introducing the achievements of biomedical ethics in the family doctors' practice. The authors used their own experience in the creation of a national model of family medicine with consideration of the bioethical issues within the framework of the international projects *Matra* (the Netherlands) and AIHA (the USA). The bioethical issues were reflected in the additions to the programs of the family doctors graduate

and postgraduate education, which were suggested during the implementation of the mentioned international programs.

We had some difficulties in the comprehensive exposition of the material, caused by rapid progress in medicine, biology, philosophy and jurisprudence, and by permanent changes in the nature and depth of bioethical problems. This textbook is aimed at promoting further development of bioethics conception and application of its postulates in the clinical practice and in medical and biological research and experiments, carried out in Ukraine. The importance of deep and complete mastering of the bases of bioethics for the medical students of the higher educational institutions of the IV level of accreditation is obvious. The authors hope for a dialog with their colleagues, scientists, interested professionals, and representatives of public organizations and public institutions. Constructive critical remarks will be accepted with deep gratitude as a subject for fruitful discussion and correction of possible failings. The English edition is translated with taking into account the previous Russian translation peculiarities.

Section I

THE OBJECT, THEORETICAL BASES AND STAGES OF DEVELOPMENT OF BIOETHICS AS A DISCIPLINE

"A doctor-philosopher is like a god."
Hippocrates

THE OBJECT AND THEORETICAL BASES OF BIOETHICS

The subject of bioethics is the complex of disputable ethical questions, which can be identified in the process of medical practice, in the course of biomedical research and experiments or in the combination of both these types of professional activity. The term "*bioethics*" means systematic analysis of human actions in biology and medicine in the light of moral values and principles. According to academician Yu. I. Kundiev's vivid expression, "bioethics is an organic integration of modern achievements in science and medicine with spirituality". Bioethics includes a vast circle of socio-economic, moral, ethical and legal problems, the content and depth of which constantly change in the course of biology, medical science and practice development. The characteristic task of bioethics consists in comprehensive analysis of such problems with the purpose of their clarification and solving. Besides the term "bioethics", another word combination, "*biomedical ethics*" is often used. Both these terms became common in the modern language and can be used as synonyms, but there are some distinctions between them. The term "biomedical ethics" focuses on the problems related to practical medicine. In this context the term "bioethics" envelops a wider scope of the disputable questions, including social medicine, legal issues in biology, and the ethics of biomedical investigations and experiments. In any case, we should understand "practical medicine" in a wide sense, including both the doctors' professional activities, and other specialists' activities related to the public health services.

The professional conduct of medical workers is the priority object of bioethical studies. Its formation in 1970-s became a natural result of the medical ethics development. Bioethics formed on the junction of different sciences, such as medicine, biology, philosophy, sociology, psychology, professions and religion studies, pedagogies, management, and jurisprudence. The term "bioethics" was introduced by V. R. Potter in his article "Bioethics, the Science of Survival" (collected articles "The Prospect of Biology and Medicine", 1970) and in his book "Bioethics, a Bridge to the Future" (1971). The conception of bioethics appeared in the atmosphere of ethical accusations of medicine and science, which arose in late 1960-s. The term "bioethics" was suggested by V. R. Potter in order to stress the necessity of new ethical approach, which would resist the challenges of scientific and technological achievements and provide the survival of humanity in the post-industrial society.

Bioethics is a science concerning the laws, principles and rules which regulate the medical and research workers' professional conduct. It provides safe implementation of new medical technologies and reminds doctors and scientists about the impermissibility of doing harm to people, their offspring, all the humanity and biosphere on the whole.

Bioethics is a subsection of a more general science — ethics. Ethics in its nature is a philosophical discipline. As a section of philosophy, ethics can be defined as the "philosophical study of morals". As such, it should be dissociated from the "scientific study of moral", which is designated by the term "descriptive ethics". The purpose of descriptive ethics consists in receiving empiric knowledge concerning morals. The specialists in the field of descriptive ethics describe the existing moral views and try to explain them on the basis of their psychological or sociological origin. The moral views, as well as other aspects of human experience, provide the psychologists and sociologists with a wide range of phenomena, which need explanation. For example, psycho-analysts can explain some features of sexual morals using Z. Freud's theory; and sociologic questioning shows that the position of certain social groups concerning euthanasia are related to their religious world view.

Further in this book the term "ethics" will be used only in the philosophical meaning, different from the subject of descriptive ethics. Philosophers usually subdivide ethics into normative and meta-ethics. Normative ethics aims at defining, which human actions are correct from the moral point of view, and which are not. The tasks of meta-ethics consist in establishing the nature of moral views and determining specific methods, suitable for the confirmation of separate moral views and theoretical systems rightness. Probably, the discussions in the field of normative ethics, to a certain degree, concern the meta-ethical reasoning and can not be separated from

them totally. As we see, there are some differences between normative ethics and meta-ethics, but it is especially important to understand that there are pronounced logical distinctions between the normative and descriptive ethics. While descriptive ethics tries to depict and account for those moral views which are actually *already accepted*, normative ethics tries to establish, what moral views *are justified* and thus *must be accepted.* The task of general normative ethics consists in the development and grounded confirmation of a generalized theory of moral obligations, otherwise speaking, of an ethical theory which would give a general answer to the question: "What is right from the moral point of view and what is wrong?" The task of the applied normative ethics, unlike general normative ethics, consists in making decisions on specific moral problems, for example, whether abortions have moral justification, and if they do — on what conditions.

In the light of the described distinctions, bioethics can be identified as a branch of applied normative ethics. The task of bioethics is to solve ethical problems related to medical practice, biomedical research or to both these fields. Ethical problems related to other aspects of life, naturally, belong to other sections of applied normative ethics. For example, business ethics concerns ethical problems which arise in the process of different types of business activity. It is important that all private problems discussed in applied ethics are normative by their nature. It has to answer questions concerning ethical rightness or wrongness of a concrete practical action and its moral justification. The applied ethics does not try to find out, what moral views people have in reality. This is the task of descriptive ethics. The applied normative ethics, as well as the general normative ethics, is directed at deciding which moral views are justified.

The characteristic questions bioethics tries to answer are: "Does a doctor have a moral obligation to inform the patient that his illness is incurable?", "Can the violation of a medical secret be morally warranted?", "Is there a moral justification for euthanasia?", "Is substitute maternity moral?", etc. All these questions belong to the field of applied normative ethics and are directed at the evaluation of separate actions and practices. Other bioethical issues concern ethical justification of laws. For example, are the laws prohibiting or limiting the abortions just from the moral point of view? Are laws which prohibit active euthanasia needed? Should specific laws, allowing to hospitalise a person to a psychiatric clinic without his/her consent exist? Such questions show that bioethics has certain relationships not only with general normative ethics, but also with socio-political philosophy and philosophy of legislation. This fact is demonstrative of the inter-disciplinary nature of the bioethical science within the framework of philosophy. The inter-disciplinary nature of bioethics can also be confirmed by the fact

that the debatable problems are often examined not only from the point of philosophical view upon morals (ethics is a science concerning morals), but also from the perspective of theological estimation of morals. The principle difference consists in the fact, that philosophical arguments exclude the recognition of any religion or religious faith, while theological arguments on the whole stay within the limits of a specific religion. However, the most essential sign of the inter-disciplinary nature of bioethics consists in its connection with medicine and biology. The achievements of medicine and biology act a major part in the development of bioethics, the nature and orientation of philosophical ideas. It is necessary to acknowledge the exceptional value of the doctors' and research workers' participation in the bioethical discussions. It provides the possibility of philosophical analysis in accordance with the realities of medical practice and biomedical investigations (T. A. Mappes, D. De Grazia, 2001).

The development of bioethics as a science was promoted by theoretical developments in the field of fundamental principles of this discipline. An exceptional role in the determination of an original approach to this problem belongs to T. L. Beauchamp and J. F. Childress. In their original publication "The Principles of Biomedical Ethics" (1979) they formulated four principles of this subject:

1. The principle of respect towards autonomy presupposes respect towards personality and protection of people with limited autonomy (children, patients with mental disorders, etc.).

2. The principle of non-harming implies, that a medical worker must not act in a way, that is practically harmful to a patient.

3. The principle of aid and comfort says that a medical worker must operate on the behalf of a patient's wellbeing, show mercy and benefaction.

4. The principle of justice is directed at the observance of just distribution of both social welfare (for example, possibilities of effective health protection) and social duties (for example, taxes).

Bioethical training should be carried out continuously during all the period of a specialist's professional activity. The interdisciplinary nature of bioethics presupposes sociological understanding of the medical and biological communities. It also implies psychological understanding of the researchers', doctors', medical workers', and patients' needs, as well as the types of impacts they are exposed to. A historical understanding of the sources of bioethics theory and practice is important. The mastering of the ethical analysis methods, as they are understood by philosophers and theologies, should be combined with understanding of these methods limitations, when they are applied to concrete practical situations. Every specialist engaged in biomedical ethics needs to have direct contact with the ethical problems which arise in medicine and biology. It is very important for biomedical

ethics to develop inductively, i.e. proceeding from the problems realized by doctors and research workers, who count on co-operation in determining the methodological strategy and decision-making to solve these problems. There is an interesting opinion that medicine has saved ethics from dying. The question is that the philosophers', physicians', lawyers' and other professionals' co-operation had serious and irreversible impact on the methods and content of philosophical ethics. Bringing the materials of concrete life situations into ethical discussions compelled the philosophers to return to Aristotle's positions, which were not used for such a long time (S. Toulmin, 1982).

The forming and development of bioethics is directly connected with the development and transformation of classic ethics on the whole and medical ethics or medical deontology in particular. The new science has raised and is trying to solve problems related to the preservation of the human nature, protection of the Earth biosphere, and the humanity survival. A specialist in the field of biomedical ethics works in three basic directions:

1. Finding problems liable to moral estimation (the determination of the subjects of discussion).

2. Systematic analysis and discussion of human actions in biology and medicine in the light of moral values and principles (the methodological strategy).

3. Helping the doctors and biomedical research workers to ground correct actions on the basis of biomedical ethics principles and theories (the decision-making process).

V. Potter, the founder of bioethics, has conceptually developed its basic directions. He considered that bioethics should embrace the whole complex of knowledge concerning living creatures and study not only the medical problems, but also issues of ecological ethics. "It is quite clear, — wrote V. Potter, — that bioethics should be built on a multidisciplinary basis, and I offer two regions, the interests of which are seemingly different, but which need each other: they are the medical and ecological ethics. They intersect in the sense, that the medical ethics is mainly related to the patients' and doctors' direct decisions and optional choice in their aspiration to prolong human life... Ecological ethics has stable beliefs in relation to what we should do to save the ecological systems in a form consonant with the protracted existence of the humanity".

The idea of such global bioethics which offers to achieve the "*acceptable survival*" of a stable society in a healthy ecological environment began to be realized practically since 1990-s. In 1970-s and 1980-s bioethics, in fact, developed within the limits of medicine and biomedical research. In 1970-s and 1980-s the terms "bioethics" and "biomedical ethics" were prac-

tically synonyms (the nature of insignificant distinctions between them was discussed at the beginning of this chapter).

In 1980-s a suggestion was formulated: to separate the so-called "clinical ethics" from the general biomedical ethics. This suggestion did not get much support, though. It is generally known, that the appearance of bioethics was based on the newest scientific achievements in the field of biology, genetics, gene engineering, transplantology and clinical testing. Certainly, all these fields were *clinical* and presupposed contacts of doctors and patients. However, the majority of doctors did not do research work, a relatively small number of them studied medical genetics, and quite a few were engaged in transplantology. At the same time, practical doctors regularly encountered the problems of seriously ill and dying patients and other ethical problems of modern medicine. These routine everyday ethical problems of practical medicine were attributed to the "clinical ethics", whereas biomedical ethics mainly solved the problems of high medical technologies and social medicine (M. Siegler, 1979).

Bioethics became global in its nature in 1990-s owing to the globalization of economy, science and culture, characteristic of the modern society. The reasons of the world globalization are internationalization of economy, development of a united world communication network, decreasing of the national states role, and the activation of trans-national non-state organizations (ethnic diasporas, religious denominations, ecological associations). The process of globalization in the modern society is ambiguous, it is estimated in quite different ways, and it sometimes causes serious ideological contradictions and even collisions. However, globalization is undoubtedly useful for the bioethics, because it is directed at providing the survival of humanity on the basis of creating an interlink (bridge), necessary for the connection of the medical and ecological ethics in a world scale.

Presently global bioethics develops in the followings directions:

1. Ethics of the medical professions (doctors, nurses, technical employees, administrators).

2. Ethics of the clinical research and experiments on animals with therapeutic and non-therapeutic purposes.

3. Social ethics of medicine (social justice, social-ethical obligations, allocation of health protection resources, bioethical problems of the medicine of labour, sports, multinational society, and demographic development).

4. Ethics of the environment protection.

5. Ethical estimation of biological law as the legal regulation of intrusion into the human organism, human genome and the biosphere, a part of which people are.

6. Ethical modification of certain population groups behaviour on the basis of development and introduction of global educational programs with

the purpose of prevention of some diseases, related to improper life-style and human conduct (for example, HIV infection/AIDS, infectious diseases which spread through water, food or air, etc.).

High and steady interest towards bioethics in the whole world, including Ukraine, is not casual and can not be considered a display of quickly changing fashion. Bioethics was not only an answer to the problems related to the newest achievements in science and technology; its development was also conditioned by serious social and ideological changes in the modern society.

The ideas of post-modernism appeared and spread widely by the end of the XX century. The post-modernism tendencies of the contemporary post-industrial consumer society can be characterised with the lack of canonised rules and systems, with the disappointment in ideals and values of the Renaissance and Enlightening. The main ideas of humanity — the faith in progress and emancipation of personality, the focus on scientific knowledge, the belief in the boundlessness of human possibilities and the triumph of reason — were lost. The post-modernism ideology had influenced not only the ethics, but also the people's world outlook, life style, science, art and religion.

Today the theories of modernism and post-modernism are replaced by the idea of globalization, which, unfortunately, also can not help in finding answers to the problems, related to the unevenness of different regions of the planet development, the "westernisation", and the decrease of national self-identification. The development of global bioethics as a special world outlook of the end of the XX-th century was conditioned by people's awareness of the possible de-humanisation of science, oblivion of authentic humaneness, and the isolation of people from the veritable life, which they perceive only indirectly in the process of cognition. The events which have occurred by the end of the last century promoted the beginning of the public discussion of the moral responsibility for the wide application of the newest technologies. As S. V. Vekovshinina (2003) justly points out, the global bioethics, to a certain extent, is a result of interpenetration and cross-coupling of different cultures and different ethical systems. Its origin, along with other cultural phenomena, became the starting point in the development of a new human self-consciousness characterised by democratic views, de-ideologisation, tolerance, pluralism of tastes and ideals, and multiplicity of ethical paradigms. As a multidisciplinary school, global bioethics aims at overcoming narrow-mindedness of the former scientific knowledge philosophical and theoretical bases. It criticizes one-dimensional traditional philosophical axioms, and aspires to create qualitatively new fusion of different ethical points of view. In the field of global bioethics scientific analysis there is a vast set of ethical, utilitarian, deontological, communicative, and theological governing rules and principles, which sometimes conflict with each other.

The modern society professes increasing interest to the methods of ethical control of the physicians' and researchers' activities, carried out on the basis of normative documents developed and approved by different international organizations. The most important of these documents is the Convention On Human Rights and Biomedicine. It was approved by the European Council and concerns the protection of human rights and dignity in connection with the practical application of accomplishments in the field of biology and medicine.

Legal registration of the biological law as a mechanism of regulation of research in the field of medicine, biology and ecology become an objective reality in the life of the modern society. The transition from ethical values to legal norms grounds the necessity of a methodologically correct determination of relations between the bioethics and law (fields of responsibility, autonomy, and coexistence of these disciplines). Their task consists in creating an effective, socially just mechanism of control and regulation of the medical and biological intervention into the human organism and its environment. Once J. H. Poincaré (1910) considered that the idea of states parliaments making competent decisions concerning the issues of scientific research was ridiculous. To his opinion, it was "necessary to follow one's own conscience; any legal interference would be inappropriate and somewhat ridiculous". Things have changed cardinally: our modern society discusses the need in a scientific tribunal, which would settle the disputable questions and prepare a statute-book, regulating issues of research. Scientific journals have a right to withhold from publishing the results of research which did not undergo ethical examination.

The processes, related to the creation of a market economy and the development of a democratic and humanistic society in Ukraine have an additional impact on the development and becoming of bioethics. The medical science and health services in our country are turning into one of the priority spheres of public life. The relations between doctor and patient are being modified owing to the growing medical knowledge of the population; people begin to understand, that their health and the health of their children depends primarily on their own care and responsibility. Owing to the introduction of insurance medicine and changes in the legal base, the medical professions become a sphere of legislative regulation and everyday legal control. A doctor's social role is changing gradually: now he must not only carry out the orders of his employers, but also make responsible decisions within the framework of the system producer (services provider) — user of products, and in accordance with the laws which protect the users' rights.

Global bioethics is open to changes and modifications. The ideas of different types of secular bioethics and its religious versions coexist: there are Orthodoxy, Catholic, Protestant, Judaic, Islam and other versions of

bioethics. One of the characteristic features of global bioethics is its deep connection and closeness to the Christian attitude. It presupposes the necessity of careful attitude of people towards every display of life as a higher value and the "veneration for life" (A. Schweizer).

The multidisciplinary and "multi-style" nature of global bioethics determines the possibility of moral orientation in the modern multinational society and finding non-standard decisions of individual ethical problems. The social orientation of global bioethics, its orientation at the observance of principles of justice, veracity, autonomy of personality, non-harming, and informed consent determine the possibility of creating an organic and steady connection between the scientific knowledge and moral values with the purpose of the humanity survival and the preservation of its environment. The role and importance of global bioethics in the modern world are especially clear from the historical perspective.

THE HISTORY OF THE MEDICAL ETHICS DEVELOPMENT

The moral development of the humanity has proceeded for millenniums, and it is still far from completion. The sources of the medical ethics are related to the formation of general ethics and the development of professional medicine. In the most general lines (and in a rather relative way) the history of medical ethics can be divided into five stages:

I — the stage of the fundamentals of the subject formation;
II — the stage of the corporate medical ethics development;
III — the deontological stage;
IV — the bioethics stage;
V — the nooethics stage.

The beginning of the first stage of the medical ethics development goes back hundreds of ages. A primitive moral, which declared in the forms of totems and taboos: "you can do everything, that is not forbidden", appeared in the epoch of neolith (in the VIII-th — III-th ages B.C.). In the same period, when the primitive human herd developed into a family community and engaged in production (cattle breeding and agriculture), medicine began to be formed. Presumably, it was then, that the physicians and witch-doctors for the first time compared the results of their professional activity with the moral concepts of good and evil.

The history of medical ethics includes ancient shamanism, views and precepts of the Egyptian doctor and priest Imchotep (3000 years B.C.),

and the first medical code developed by the Babylonian king Khammurapi (2500 years B.C.). Since the ancient times the art of doctoring was evaluated by all cultures in the moral and religious aspects. The capabilities of a healer were considered to be a charisma. Medical manipulations were accompanied with prayers and rituals. In ancient Greek and Roman civilizations priests in the temples devoted to gods-promoters of medicine, such as Asklepius, were doctors. The god of medicine Asklepius was considered the founder of a famous medical school from which the great Greek doctor Hippocrates the II from Scythes had graduated. He was born in 460 B.C. and lived for 83 years (from other data — for 104 years). Hippocrates insisted that doctoring was a kind of scientific activity based on watching the course of illness and estimating the efficiency of treatment attempts. He separated medicine from religion, but not from the moral sources. Hippocrates considered that "love towards the medical art is love towards the humanity". A doctor must enter a patient's house with intentions to do good and avoid harm and injustice.

One of the most ancient medical ethics documents known as the "Hippocratic Oath" is related to the name of Hippocrates. Hippocratic ethics is based on the idea of respect towards the patient and an obligatory requirement that the treatment would not cause him/her harm or unnecessary pain. A doctor was obliged to refrain from having intimate relations with his patients, divulging their secrets, making abortions, and giving the patients any substances which could cause death. The doctors' selflessness and disinterestedness was encouraged. Hippocrates expressed the following opinion to his student: "I advise you to behave humanely and pay your attention to (the patient's) richness or limitedness of his resources; sometimes you should treat free of charge, considering that a grateful memory is more important than short-term glory. If you have an opportunity to help a foreigner or a poor man, you are especially obliged to render help to them". An idea of solidarity and mutual support between colleagues developed, whereas competition was reprobated. Comparing medicine to philosophy, Hippocrates asserted that all appropriate wisdom was present in medicine. This wisdom consisted in the contempt towards money, conscientiousness, modesty, simplicity in clothes, reasonableness, resolution, and accuracy. The "Hippocratic Oath" is known in history as a basis of other medical oaths and the doctors' professional codes.

During the Middle Ages and subsequent centuries the "Hippocratic Oath" was the doctors' code of ethics; it determined the rules of their professional activity. This document was included in the collection of works, known as the "Corps of Hippocrates"; it was written by the members of Hippocrates' medical school on the island of Scythes in Ancient Greece in V–IV ages B.C. Some of the works in this collection, undoubtedly, belong to Hippoc-

rates, but is generally considered, that the "Oath" was written approximately 100 years later. In the opinion of the most known researcher in this field L. Edelstein (1967), Hippocrates' traditions originate from the Pythagorean school of philosophers. Pythagoreans were interested in philosophy and religion, so if L. Edelstein is right, they had founded the medical school in Ancient Greece, which was known as the Hippocratic school. The works in the "Corps of Hippocrates", besides the "Oath", include other works on the issues of medical ethics: "The Law", "About a Doctor", "On the Propriety", "The Instructions", "On the Art", "On the Ancient Medicine". Such major issues of medical deontology, as relations between doctor and patient, doctor and the patients' relatives, the medical secret, medical errors, euthanasia, or relations between doctors, are discussed in these works.

Medical ethics was formed in the course of classic ethics development as a science about morals (from the Latin term *moralis* — dispositions, customs, habits, conduct, fashion). Socrates (469–399 B. C.) is considered to be the founder of ancient ethics. He determined morality as a person's ability to overpower natural passions and instincts, as a conduct which "becomes to a human being"; he supposed that kindness (morality) is in the human nature, whereas immoral acts are caused by insufficiency of ethical knowledge. Socrates considered the submission of people's private interests and acts to one common and higher purpose to be a higher blessing. Socrates' ethics was rational, it expressed a deep faith in reason and was based on three fundamental principles:

1) self-control, meaning independence of reason;
2) self-command, meaning domination of reason over sensual impulses;
3) freedom, meaning ability of reason to subordinate the instincts.

According to Socrates, reason is an ability to understand good and wish for good: it is the human essence and soul.

Plato (427–347 B.C.) distinguished four basic virtues: wisdom, courage, prudence, and justice. In Plato's opinion, in the process of education all virtues, and the main of them — justice — should become a basis for the development of an accomplished man living in an ideal society. According to Plato, virtues provide an order and harmony of spiritual life. Plato defined the principle of responsibility, which became the leading principle in the classic ethics. Responsibility is the requirement to every person to be fully responsible for his/her actions. "Everyone is responsible for his own choice! — Plato asserted.— God is not guilty, we are the only creators of our fate, as we build it by choosing our life style".

Aristotle (384–322 B.C.) made an enormous contribution to the development of philosophy and offered the term "ethics" (from the Greek word *ethos* — habit, moral, consuetude, disposition, character). In the wide understanding ethics is defined as a science concerning the meaning of life,

moral principles and codes of human conduct. In its beginning (for example, in Aristotle's "Nicomachean Ethics") ethics was understood as one of the major issues in the human life, as a method of spiritual hygiene. It was understood as practical philosophy (wisdom), because it taught how people should act in specific situations. These recommendations became possible owing to the development of ideas about proper behaviour. The science concerning what is due or proper is called *deontology* (from the Greek word *deon*, meaning due). A synonym of the term deontology is "normative ethics", which focuses on norms and moral laws. These norms should be discussed and worked out by the wisest and most experienced members of society. From such positions medical ethics, medical deontology, and biomedical ethics can be interpreted as the wisdom of doctoring. Hippocrates' words, which we have used as an epigraph to this section of the textbook ("A doctor-philosopher is like a god") should be understood in this sense.

In the course of ancient philosophy development steady concepts of "moral" and "ethics" emerged. They were built on a common basis, but had substantial distinctions. The term *moral*, on the whole, means an aggregate of customs and norms characteristic of a specific culture, which are recognised as rules of conduct for every person or a certain group of people belonging to this culture. On the other hand, "ethics" is understood as a kind of meta-moral, which stands above the moral and analyses its values and judgements with the purpose of developing a basis and an aggregate of fundamental principles.

The works of the great ancient Greek philosophers, especially Hippocrates' school, completed the first stage of the medical ethics history — the stage of forming the bases of the subject — which began as early as the epoch of neolith.

The second stage of the medical professional code of ethics development (the stage of corporate medical ethics formation) was related to the appearance and dissemination of monotheistic religions — Buddhism, Judaism, Christianity, and Islam. Later it was also related to the creation of university medical faculties and medical corporations. Priests and monks became the disseminators of medical knowledge. They took care of the sick and feeble, rendered medical help and followed the principles of religious moral. Religious faith became the spiritual basis of the priests' and their helpers — the sisters' and brothers' of charity — ethics. Moral postulates proclaiming the necessity of doing good, loving one's neighbours, taking care of the weak, poor, and sick people are contained in all monotheistic religions. In the Christian and Judaic traditions doctors were concerned to be the instruments of Divine healing. They were ordered to be competent and serve to the sick people, including the poor, the beggars and even the enemies. The ethical principle of Buddhism — the aspiration to do good —

as it applies to medical ethics, vividly illustrates the following Buddha's saying: "Brothers, the one who honours me, must honour a sick person". An important contribution to the development of medical ethics was made by the Islam scientists and physicians Al-Ruhavy, Ibn-abu Useibi, and Ibn-Sina (Avicenna).

The patients received help at the monasteries, from religious and civil communities of sisters and brothers of charity, different guardianships and even from the knights' orders. The regulations of these organizations included moral principles which were instrumental in the forming of medical ethics. In Ancient Russia medical activity as a special profession started approximately in the X-th century. The collection of laws "The Russian Justice" (the XI-th century) contained ethical norms which regulated the doctors' professional work. The documents of the Cyril-Belozersk monastery (the XV-th century) show that the doctors were acquainted with Hippocrates' ethical views.

The opening of several medical faculties at different universities in the X-th to XII-th centuries was a major historical event in the development of medical ethics. The independence and great prevalence of the doctors' profession, as well as the growth of its prestige, was a direct result of the medical faculties opening. A physician became a scientist and a doctor in a renewed understanding of this word. The graduating students of the medical faculties took a "faculty vow", the content of which approached to the text of the "Hippocratic Oath". The creation of medical corporations resulted in further actualization of the medical ethics problems, although corporate ethics, above all things, was directed at the defence of the medical estate interests, instead of the patients' interests. The opening of obstetric schools, gradual development of health services organization, perfection of on-line medical tutorials, establishment of an order of practical medical training, obligatory examinations and licensing was instrumental in the further development of medical ethics.

The history of the stage of corporate medical ethics formation includes the development in the early Middle Ages of the codes of "three scientific professions" (medicine, religion, right), as well as the works of T. Paracelsus, A. Z. Vezalius, U. Garvey, Malchipius, and the Code of Thomas Parsifal. The medical ethics declarations of that period, ethical codes and faculty promises of the doctors in Europe including Ukraine formed official and unofficial rules, traditions and customs of the corporate medical ethics. The first higher educational institution in Ukraine, which trained doctors, was opened in the XV-th century in Zamostye (not far from Lvov). At the medieval universities medical knowledge was always taught on the basis of deep mastering of philosophy. The Kiev-Mogilyanskaya Academy earned high authority in the field of ethics.

The third (deontological) stage of medical ethics development is conventionally dated 1834 — the time when the book by the well known English philosopher and legist J. Bentham (1748–1832) "Deontology or, the Science of Morality" was published. This scientist's desert consists in the development of the conception of deontology, known from the times of Aristotle as a science concerning one's duties and proper conduct, from the position of a philosophical trend named "utilitarianism". Bentham wrote: "The foundation of deontology is the principle of benefit..., a certain act is good or bad, worthy or unworthy, deserving or undeserving of approval depending on its tendency to increase or diminish the sum of public benefit". And further: "The wellbeing of both an individual and the society can be granted only by the readiness to selflessness which should be practiced in the interactions between people".

A substantial contribution to the conception of deontology was made by another well-known English philosopher-utilitarian John Stuart Mill (1806–1873). The ideological orientation of utilitarianism consists in "providing the greatest well-being to a biggest possible number of people", diminishing of sufferings and pain to the minimum, and the expansion of the sphere of personal freedom for the majority of people. The conception of the "quality of life" which is oriented, above all things, at quenching the pain and often at decreasing the economic expenses, corresponds to these parameters.

An exceptional role in the development of the classic theories of deontology belongs to the prominent German philosopher-moralist E. Kant (1724–1804). In his philosophical constructions he developed the ethical conception of rationalism. He supposed that the "practical reason" as a basis of ethics does not depend on any knowledge (religious or speculative). The "categorical imperative" is the basic principle of E. Kant's extraordinarily complicated ethical system. This imperative prescribes people to commit actions, which would serve to humanity and "should not be only facilities for promoting certain achievements, but at the same time should always be the goal". E. Kant's deontology represents ethics of respect toward others and oneself.

An English philosopher W. Ross (1930) made another important contribution to the development of deontology. His theory was devoted to making deontological decisions in the situations of "obligations conflict", and subsequently it played a significant role in the forming of the modern bioethics. The starting point of W. Ross's reasoning concerned situations in which one group of ethical obligations contradicted another. To find an adequate solution of situations related to the conflict of obligations the philosopher offered the concept of "*prima faces*" (conditional) obligations. W. Ross asserted that there is no arbiter which can determine their priority in each

case. He included the following cases in the group of conditional obligations:

1) the obligation of loyalty — to keep promises, respect contracts and agreements, tell the truth;

2) the obligation of compensation — to make up for harm caused to others;

3) the obligation of gratitude;

4) the obligation of benefaction and mercy;

5) the obligation of not harming;

6) the obligation of justice;

7) the obligation of self-esteem.

According to W. Ross, when there is a conflict of two (or more) conditional obligations, the choice is made on the basis of the concrete circumstances analysis. There is no clear and universal rule, whish would regulate one's actions in difficult cases, so people should make "weighted" and "appropriate" decisions in each case.

In the process of the deontological theories development and deepening, moral requirements and norms, the principles and postulates of one's duty worthy fulfilment were considered from different philosophical systems positions. It is interesting that originally deontology as a section of ethical theory embraced the content of various professions and specialities. However, as time passed it began to consider ethical problems of medicine to a greater extent than of other disciplines. As a result, by the end of the XIX-th century medical ethics was frequently named medical deontology. For this reason, the stage of medical ethics formation which corresponded to the period of intensive development of deontology (beginning with J. Bentham's classic works) was called the deontological stage. Deontology as a doctrine concerning the moral duties in general became an applied science, which studied the implementation of principles and norms of medical ethics in different branches of medicine, a school of medical humanism and moral professionalism. This doctrine struggles against the commercial trends in medicine, for the observance of the patients' interests and the physicians' professional rights.

Prominent Ukrainian medical scientists and practical doctors also made a considerable contribution to the forming and development of the deontology theory and practice. The list of these specialists includes M. Maksimovich-Ambodik, D. Samoylovich, N. Pirogov, V. Obraztsov, N. Strazhesko, F. Yanovskiy, D. Zabolotniy, A. Bogomolets, M. Yasinovskiy, N. Amosov and many others. Unselfish service to other people and self-sacrifice in the execution of professional duty was characteristic of them all. We should stress the significant contribution to the development medical deontology made by the well-known surgeon N. Pyrogov, who developed the code of

medical nurses' ethics, drew attention to the co-operation between doctors and the medical administration, and formulated the principle of continuity of medical education in his famous phrase: "To learn and to live means one and the same thing".

An enormous role in the development, popularization and distribution of the medical deontology principles belongs not only to separate philosophers and medical scientists, but also to professional medical associations, governments and non-governmental agencies, legislative bodies, to the Church, prominent figures in science and art and to the wide public.

The results of the Nuremberg Proceedings, at which the crimes of doctors-fascists in the Second world war were denounced, gave an additional impulse to the development of medical deontology. The shocked humanity learned the truth about the inhuman actions of Nazi physicians. 70,000 persons were killed by them on racial, social and medical grounds. It was found that they had developed an extraordinarily effective program of euthanasia. It also became known to the world that some doctors, despite the "Hippocratic Oath" they had sworn, executed villainous experiments on prisoners of war and on persons deported from countries occupied by the Nazis, having disgraced the profession of physician by their actions. It was at the Nuremberg Proceedings that the world put the honesty of doctors and the medical ethics to doubt for the first time. Not so long ago it was found out that during the Second World War similar villainous experiments were made by doctors in Japan. The necessity of developing international codes of medical ethics became clear to the international community. The Geneva declaration (1948) and the International Code of Medical Ethics (1949) were approved by the World Medical Association in the atmosphere of emotional animation and mutual understanding. Doctors were among the first people, who raised their voices against the production, distribution and use of bacteriological, chemical and nuclear weapons.

An exceptional role in the analysis of the deontological stage of medical ethics development and forming the philosophical and analytical base of its next stage — bioethics — belongs to an outstanding person, one of the greatest people of the XX-th century — Albert Schweitzer (1875–1965). In his ethics of "reverence toward life" there is no distinction between a more valuable or less valuable life, a higher or a lower one. Considering every form of life sacred and inviolable, A. Schweitzer criticized the anthropocentricity and carried the biblical commandment of "Thou shalt not kill" beyond the narrow limits of inter-human relations. He had a complete right to say: "My life is my best argument". A. Schweitzer, a man of versatile interests, was known not only as a talented doctor but also as a thinker, humanist, philosopher, theologist, priest, musician, musicologist, writer, journalist, social worker and philanthropist. He was awarded the title of a Nobel

laureate. His contribution to the development of medical ethics is enormous and consists in the creation of a new style of thought which includes the conception of the environment protection. The new way of thinking meant the admission of all the people's responsibility for the preservation and continuation of life on Earth. The survival will be possible if the changes of mentality are ahead of the rates of the technical progress; if the precipice between the poor and the rich diminishes; if the expenses on the armament go down, and the economic progress is not accompanied by destruction and degradation of the environment.

A. Schweitzer can be justly considered the founder of the ecological science. He realized the problem which confronted the humanity in the XX-th century: the exponential growth of knowledge is not accompanied with the growth of wisdom necessary for the management of this knowledge.

A. Schweitzer's ethics, characterized with universalism and globality, was directed at overcoming this discrepancy and the search of a way out of the XX-th century spiritual crisis. A. Schweitzer saw the reason of the modern ideological crisis in the opposition of the personal ethics and the ethics of society. According to A. Schweitzer, all the variety of ethical systems and ethical world views can be reduced to two basic types: ethics of renunciation and ethics of perfection. The ethics of renunciation is socially-utilitarian in its nature and implies that every individual should sacrifice his/her interests for the sake of others and the society as a whole. The other type is the ethics of a moral personality self-perfection. A moral personality constantly enters into polemics with the ethics of society because of the distinctions in the understanding of humanity. A. Schweitzer considered that the ethics of a moral personality should be on the first place, and the ethics of the society can become moral only by acknowledging individual ethical values. He considered the assertion, that the ethics of a moral personality and the ethics of society can not be united in a single system of ethical values, a greatest error.

The fourth stage of the medical ethics development and forming — the stage of bioethics — began in 1970, when W. R. Potter's works were first published; he became the founder of a new science (the bioethics) and defined it as a "way to survival" and "a bridge to the future". As the new stage of medical ethics development, bioethics is directed at findings ways of active humanization of medicine and the medical and biological science by confronting medicine and biology with human rights. Bioethics aims at the protection of the physical, mental and spiritual integrity of the human beings and their genome, the animal and vegetable kingdom, and the environment. It is a complex of measures on systematic analysis and co-ordination of human actions in the field of medicine, biology and ecology from the perspective of universally recognised moral values and principles.

The formation and development of bioethics was a direct result of the practical implementation of scientific and technical revolution achievements in the conditions of a deep ideological crisis and the increasing load of global ecological problems.

Enormous success of the medical and biological sciences complex generated a great number of serious moral problems. Human beings try to spread their control over their own evolution and claim not only to the maintenance of their life, but to the improvement and changing of their nature according to their own understanding (!). In this situation discussions concerning the ethical basis and moral right of such actions are inevitable. The ethical problems of clinical trials and experiments on animals, gene engineering, transplantation of organs and tissues, new reproduction technologies, and euthanasia became topics of intensive discussion and analysis.

A deep spiritual crisis, devaluation of moral values, consumer nature of the civilization, lack of global ideas, technocracy of thinking, pragmatism and cynicism are characteristic of the modern society.

In the XX-th century the humanity was confronted with catastrophic consequences of the global ecological crisis. This principally new phenomenon set the questions of the humanity physical survival and the development of the human civilization. This critical phase of relations and contradictions between the society and nature was caused by precipitate growth of natural resources consumption, changes of landscapes, creation of a new anthropogenic environment and the disturbance of the dynamic equilibrium in the biosphere at different levels of its organization. It became obvious that the solving of the global ecological crisis problem is related to the solving on the ethical basis of the issues concerning the combination of economic development aims with the maintenance of ecological equilibrium and resource stability.

W. Potter's desert consisted in constructing a "bridge", an "interlink", an organic connection between such principally different disciplines as biology and ethics. Natural sciences from the beginning of their existence were oriented at objectivism as their best ideology, at the study of the objective reality without its subjective emotional or morally-ethical estimation by people. The essence of the historically formed deep conflict between naturalism and humanism consisted in a tendency manifested by the descriptive and experimental science to ignore any information and knowledge which are beyond the limits of the competence of its methods of research.

According to W. Potter's plan, the bioethics represents not only a bridge between different disciplines but also a "bridge to the future", necessary "for the connection of medical ethics and environmental ethics in a world scale, aimed at providing the survival of the mankind". It is the "global

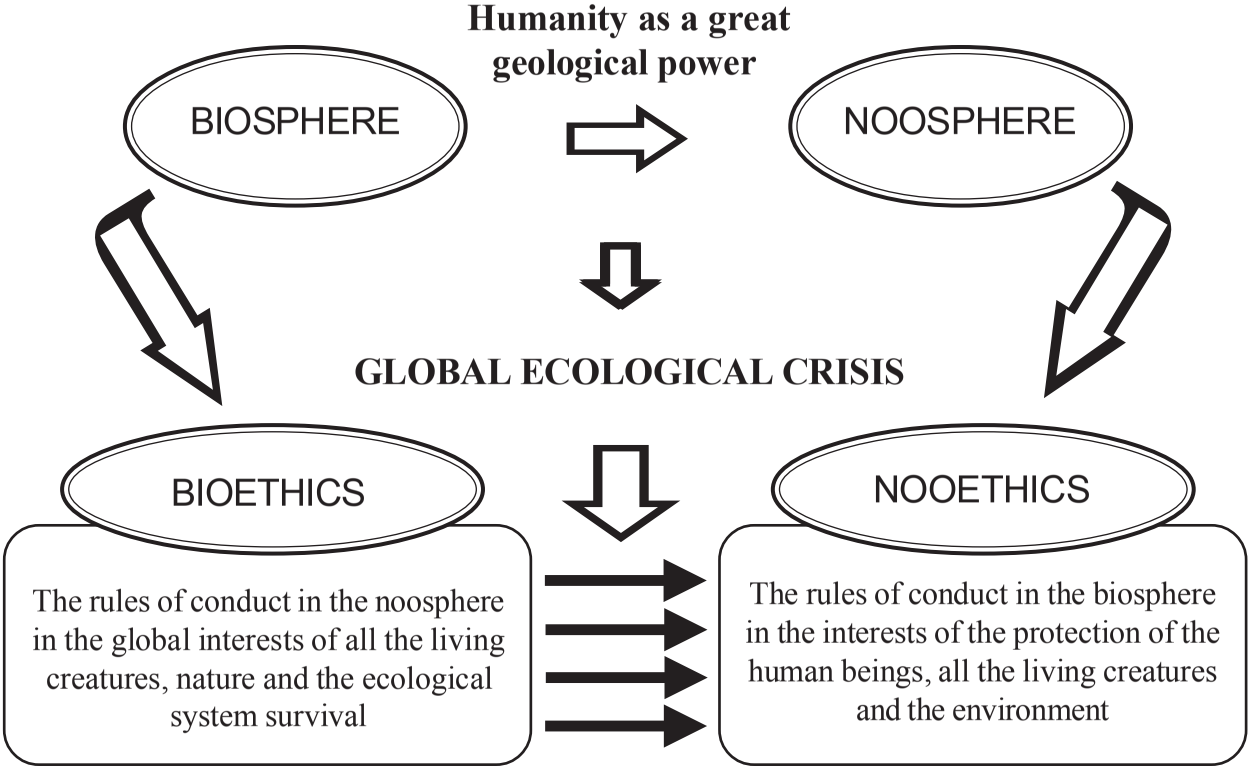

Fig. 1. Academician Vernadskiy's conception

bioethics, based on intuition and reason (logic), supported by empiric knowledge of all the branches of science, but especially by biology", which can and must provide the "long-term survival of the humanity as a species in a normal and stable civilization". Thus, ethics which historically was an exceptionally human-centred field of knowledge and studied the relations between people, expanded its area of interest to all the living creatures (A. Schweitzer), and later the concept of morality spread to the nature on the whole (W. Potter).

The development of different theories (such as principalism, liberal ethics, utilitarianism, contractualism, and socio-biology) was instrumental in the formation and development of bioethics. The philosophical analysis and wide discussion of practical issues on the basis of bioethical principles, methods and theory began an important process — the forming of ethical thinking. The Committees on Bioethics at different levels (from the local to national ones) became major instruments of bioethics principles realization. The task of these Committees consists in the bioethical examination of all projects which presuppose research on people. The basic principle of their activity is respect toward a healthy or sick person's life and dignity, his rights and interests. The rights and interests of an individual in all cases must be valued higher than scientific or social interests. Detailed recommendations on the organization, functions, rights and duties of the Committees on Bioethics were developed by the WHO Committee of Experts on the basis of the generalization of their practical experience in different countries. In Ukraine the Commission on the Issues of Bioethics at the Cabinet of Ministers of Ukraine, Committees on Bioethics at the Ministry of Health, Presidiums of the National Academy of Science and the Academy of Medical Science of Ukraine, and numerous committees on medical ethics at different medical institutions were created and execute their work.

The publication of numerous books, textbooks, encyclopaedias and periodicals on bioethics, courses on this subject at the universities, organisation of congresses, conferences and symposiums are indicative of intensive international development of bioethics.

We think that today medical ethics is at its next, fifth stage of historical development, conditioned by the irreversible changes of balance in the relationship between the mankind at its present level of civilization and the nature. The philosophical and world outlook bases of this stage were determined by academician V. I. Vernadskiy's conception on the Biosphere and its transformation into the Noosphere as a result of the humanity activities as a great geological power (see fig. 1).

The retrospective estimation of the history of bioethics indicates that in 1970-s it attracted attention to the protection of human rights, in 1980-s it was directed at the problem of the quality of life improvement, and in

1990-s it attained the nature of global bioethics. The biosphere has its own control mechanisms, which are called to protect the Earth as a celestial body, all the biosphere and the humanity. The biomedical and ecological ethics as two constituents of the global ethics have developed as a result of the humanity conscious aspiration to survival by way of the biosphere preservation on the basis of uniting modern achievements of science and practice with the morality and spirituality, and by the protection of the biosphere natural control mechanisms. Unfortunately, in spite of the awareness of the risk of a global ecological catastrophe, the active work of bioethics establishments, governments, parliaments, governmental and non-governmental agencies, doctors, lawyers, teachers, environmentalists, Church and wide public, the negative tendencies of the biosphere degradation were not overcome, and the humanity entered the XXI-st century with an increasing load of unsolved problems. Today it is clear to the habitants of planet Earth, that the humanity has damaged the control mechanisms of the biosphere. While remaking the nature and environment, people by the consequences of their intellectual work have changed the life conditions on the planet, and created their noosphere, which unlike the biosphere, does not have its own control mechanisms.

Unfortunately, in the new reality the former bioethics principles, methods and theories will not be adequate and effective enough. In the conditions of the realized noosphere the interactions of individuals or the humanity as a whole with the objects of living and inanimate nature to a constantly growing extent take place not only directly, but also indirectly, through the modified biosphere.

If the human activity in the noosphere is not regulated by new ethical principles, the consequences of the modern noosphere crisis may have global and catastrophic nature. For the preservation of all the living creatures, the nature and the ecological system as a whole this new ethics must become the Noo-ethics, meaning a set of rules of behaviour in the Noosphere, which would be maximally instrumental in global interests of all its constituents: the Earth, the mankind and the biosphere transformed by the humanity. The Noo-ethics is intended to become one of the numerous control mechanisms of the Noosphere, designed to provide its stable existence and development. The creation of the noo-ethics can be considered a strategy of new ethics development, and a device for the humanity survival at the modern stage of its existence. As the higher stage of bioethics development, it should be integrated with the ethics as a section of philosophy and become its inalienable and very important part. The noo-ethics will be instrumental in the further development of medicine and the medico-biological science, and this fact allows to name the modern stage of medical ethics development the noo-ethical stage (V. N. Zaporozhan, 2004).

Section II
THE METHODS OF BIOETHICS

> "Life is short, art is vast, occasion is precarious, experience is deceitful, judgement is difficult."
>
> *Hippocrates*

For an epigraph to this section we chose one of the most notorious Hippocrates' aphorisms, which is especially well known in the Latin translation: "Vita brevis, ars longa, occasio autem praeceps, experientia fallax, judicium difficile". This aphorism reflects the complexity, relativity and endlessness of the cognition process, and this concerns biomedical ethics as science to a full extent.

Bioethics, which according to academician Yu. I. Kundiev's expression, became a sign of civilization in the modern society, originally concerned only urgent problems of everyday clinical practice. Although clinical ethics remains the kernel of bioethics, the sphere of bioethics has extended to the scale of a section of applied normative ethics, which examines from the moral point of view admissibility or impermissibility of actions towards a living being or the environment. The field of bioethics has included new spheres, such as conceptual analysis of bioethical principles, empiric estimation of medical workers' actions, ethical estimation of the health protection policies and the interdisciplinary analysis from the position of such disciplines as anthropology, literature and history. Besides, the specialists in the field of bioethics have carried out critical assessment of the ethical analysis methods, which they have used.

Not a single systematic ethical theory became dominant in bioethics: different philosophers and theologists used conceptions and arguments from different perspectives of morality. Such a situation is not surprising, because in the applied fields of knowledge (and bioethics is an applied science) methodological discussions usually do not take the central position.

On the other hand, grater freedom in the choice of methodological basis allows to focus more attention on the essence of the examined problem.

An ethical theory offers a construction, which can be used to establish, which human actions are morally acceptable and which are not, and in order to define from the moral point of view, which traits in an individual's character should be considered good, and which bad. The theories of proper or improper actions have attracted most attention in the XX-th century and are often used in biomedical ethics. An ethical theory offers a set of moral standards (or, in some cases, one obligatory moral principle), which allows to assess the rightness or wrongness of the moral choice of human actions. The same type of question can be asked in regard to any of the great number of ethical theories: what are the criteria of its acceptability? A theory must be consistent, complete, clear and sufficiently simple for use with practical purposes. In accordance with these demands we can formulate two main principles:

1) The propositions of an ethical theory should closely correspond to our life moral experience;

2) An ethical theory must provide effective guidance in the situations of moral dilemmas.

Surely, the presented criteria can not be used directly and mechanically in the estimation of ethical theories adequacy. For example, the proposition, that an adequate ethical theory must correspond to our moral life experience, does not mean that any deviation from the "generally accepted" morals must be understood as wrongness of the ethical theory in question. It is more probable that we should reassess our moral estimations in the light of the theory. By the way, in empiric research a disparity between facts and theory is sometimes settled not by changing the theory but by different interpretation of facts in the light of the existing theory.

Numerous ethical theories are used in medical bioethics in two models of ethical thought:

1. deductive analysis; and

2. inductive analysis (including the use of descriptive methods of qualitative and quantitative empiric research of bioethical problems).

DEDUCTIVE METHODS

In the deductive approach to the solving of ethical problems the analytical process goes from philosophical theories and ethical principles to a concrete case. We can say that this approach is scientific to a great extent, because it offers a procedure or an algorithm of forming ethical judgements. The first step in applying this methodological approach is the identi-

fication of the philosophical ethical theory, which is most preferable in a given case. For example, in Singer's (1980) opinion, utilitarianism is the most acceptable philosophical theory of ethics. The chosen theory should contain a greatest possible number of advantages and the smallest number of failings as compared to others. An ethics theory refers to a set of normative ethical principles. Usually such principles have rather a general than specific nature. They are universal (i.e. applicable to all individuals) and inwardly consistent. The logics of deductive analysis presuppose that the trajectory of thought goes from a general theory to a suitable ethical principle or group of principles and further — to the choice of a more specific ethical rule. The final step is the application of this rule to the concrete case which contains one or another ethical problem.

The distinguishing features of deductive reasoning are its clearness and definiteness, when a pre-condition determines the conclusion. In other words, the deductive model of ethical analysis is a strict procedure of decision-making: the theory entails certain principles and rules, which logically presuppose a particular ethical proposition in relation to a concrete case. The deductive method can be presented in the following algorithm:

1. define the preferable philosophical theory of ethics;
2. establish an appropriate ethical principle;
3. establish an appropriate ethical rule; and
4. apply the chosen rule to a concrete case.

When applying deductive analysis as the preferred philosophical theory of ethics, people most often use E. Kant's theory, utilitarianism and other similar theories, based on their principles.

***E. Kant's theory*.** In accordance with the Kantian categorical imperative, every person has a right to respect and self-esteem, and his/her actions both towards other people and towards him/herself must have humane nature: people's actions should never be only the means of achieving a certain purpose, but at the same time they should serve a purpose. According to E. Kant's ethical philosophical system everybody has direct and indirect obligations both in relation to him/herself and in relation to other people. According to the philosopher's ideas, every person's most meaningful direct obligations in relation to others are not to kill innocent people, not to lie and to act up to one's promises. Direct obligations toward oneself are to preserve one's self-esteem and not to treat oneself only as a means of achieving some purpose. The indirect obligation toward oneself, according to E. Kant, consists in self-perfection and development of one's capabilities. According to the Kantian deontology, indirect obligations toward others consist in the principle of benefaction. In the philosopher's opinion, activities on the fulfilment of one's indirect obligations should not be accomplished at the expense of neglecting the direct duties.

Although distinctions between the direct and indirect obligations are not so obvious, it is hard to over-estimate their structural value in E. Kant's ethical system. Direct obligations require performing or refraining from performing certain actions. There are no legitimate exceptions to the fulfilment of direct obligations. They remain unchanged in all circumstances, because certain types of actions are simply incompatible with the principles of respect towards personality, and thus are strictly forbidden. Indirect obligations motivate us to achieve certain goals or to be instrumental in achieving them (for example, other people' wellbeing). Distinctions between the direct and indirect obligations can be explained as follows. Direct obligations are violated, when we use people as means for reaching some goal. The indirect obligations are violated, when we do not treat a person as a goal of our actions, even if we do not use him actively as a resource (means). The E. Kant's theory as a deductive method of analysis is applicable to the problems of biomedical ethics, this can be illustrated by the following examples.

Medical specialists often discuss the bioethical problem, whether a doctor is justified in giving a terminally sick patient untruthful information on the prognosis of his/her disease. From Kant's point of view, everybody has a direct obligation toward others to avoid lies, and the direct application of this ethical theory assumes that a doctor must not lie to his patient in any circumstances.

Kantian deontology contains an important and direct answer in regard to ethics of carrying out research on human subjects. Considering that it is morally improper for all people to use any other person only as a means, it is quite clear that it is morally impermissible for a researcher to use the subject of research only as means. This answer is a base for grounding the necessity of voluntary informed consent as the basic principle of research ethics. A researcher is obliged to give the examinee all the necessary information on the project of the study (first of all, on the possible risks), which is sufficient for making a rational decision on the participation. In other words, the respect towards personality requires voluntarily informed consent of the examinee. After the researcher tells the potential subject of the study about the importance of his participation and the benefit for the society, which successful results of research may render, a question remains: does the potential subject have any moral obligations to participate in the research? Surely, he has not. In accordance with the Kantian ethics, the obligation of benefaction is indirect. A person should offer others help and assistance in need, but he does not have any obligations to implement some specific benefactions.

The bioethical analysis of suicide can also be carried out from the position of the Kantian ethical theory. According to Kant, the direct obligation

toward oneself is the duty not commit suicide. The termination of one's own life is fully incompatible with respect toward oneself as a person. While destroying himself as a reasonable creature, a person treats him/herself only as a means (of achieving a purpose to avoid discomfort or distress). In other words, suicide is an inwardly improper action, and there are no circumstances which would make it morally permissible. Adherence to harmful habits is a variant of self-destructive behaviour. According to Kant's ethics, a person has a direct obligation toward himself to avoid drunkenness, because alcohol destroys his personality and cogitative abilities, and is incompatible with respect towards oneself as a reasonable creature. The philosopher asserted that people destroy themselves in the attempt to enjoy the state of intoxication. A person who uses alcohol treats himself as a means (for achieving the purpose of pleasure).

To assess the acceptability of Kant's views as an ethical theory, we should examine the two central criteria, which were mentioned before.

Using the first criterion (accordance to the generally accepted moral rules), we can assert that many clauses of Kant's theory correspond to our moral experience in regard to such actions as murder, doing harm, lies, non-fulfilment of one's responsibilities. Kant's deontology provides a reliable basis of individual rights, related to our direct obligations toward others (indirect obligations can not provide grounds for any rights). However, many Kantian ethical ideas over-estimate the value of certain direct obligations and underestimate the value of indirect obligation of rendering help and support, at least when benefaction can prevent serious harm to other people. For example, if a man did not keep a trivial promise (for example, to return a book in time) because he helped another person in a serious misfortune, his behaviour can not be estimated as amoral (although from the point of view of Kantian ethics, the activities on fulfilling indirect obligations — in this case benefaction — should not be accomplished at the expense of neglecting one's direct duties — in this case keeping one's promise).

Using the second criterion of ethical theories acceptability (their ability to provide effective guidance in solving ethical dilemmas), we should agree that the answer is also ambiguous. Kant's theory surely provides a clear algorithm of solving ethical dilemmas, owing to the classification of ethical obligations into direct and indirect ones, and the establishment of the direct obligations priority. However, the priority of direct obligations over indirect ones is the problematic feature of the Kantian deontology. We can justly assert, that even if a theory provides an acceptably clear guidance to actions, it sometimes fails in giving correct guidance.

Theories of Utilitarianism. In the modern discussions utilitarianism is present in two variants: the theory of "action-utilitarianism" and the theory of "rule-utilitarianism".

The theory of *"action-utilitarianism",* as the basic theory, asserts the following principle: a person should act in a way, which enables him/her to attain the greatest predominance of good over evil. An action is considered moral, if, compared to other alternatives, its possible consequences provide the best balance between good and evil, acknowledged by all. In other words, people should act so as to achieve maximal benefit. What are the criteria for good and evil in the ethical analysis? Classic utilitarianism answers this question with the conception of internal values. In Bentham's opinion only pleasure in the wide sense of this concept, including all types of satisfaction or enjoyment, possesses an intrinsic value, and only pain in a wide understanding, including all types of dissatisfaction, frustration or displeasure has the internal value of evil. According to Mill's views, only the state of happiness has an internal value, and only the feeling of unhappiness is an internal evil.

The practical application of this theory has the following algorithm:

1. Define the alternative ways of solving an ethical problem.
2. Try to foresee the possible consequences (sometimes multiple and remote) of every alternative action.
3. Assess the consequences of each option from the perspective of balance of good and evil, considering the impact of the actions on each person, whom they will probably concern.
4. Choose an action which probably will result in the greatest prevalence of good over evil and define it as morally justified in a concrete situation.

If it seems possible, that both alternative actions will provide identical balance of good and evil, each of them is considered morally correct. In some situations the balance of good and evil turns negative, regardless of the people's actions. In this case it is morally correct to act so, that the prevalence of evil (pain and unhappiness) over good (pleasure and happiness) is the least.

The theory of "action-utilitarianism" can be correctly understood as "situational ethics". This theory does not define any certain types of actions as internally incorrect by their nature. Certain types of actions (for example, telling lies) can be considered morally wrong in one situation and right in another, because the consequences of actions largely depend on the circumstances. In other words, the morality of an action depends on the situation — this explains the term "situational ethics". We can use the following situation as an example of using the theory "action-utilitarianism" in the biomedical context.

A new-born infant with multiple innate developmental anomalies and serious defects of the central nervous system, which is expected to live no more than a few weeks, develops pneumonia. The neonatologist and the infant's parents have to decide, whether antibiotic therapy of pneumonia

should be started and, consequently, the child's life prolonged. The alternative decision is simply to let the new-born child die. It seems obvious, that the interests of all parts concerned in this ethical dilemma are best observed by the decision not to start the antibiotic therapy of pneumonia. Surely, the baby acquires nothing, and in a certain sense he even loses some days of life, filled with pain and suffering. The parents, who's grief will not be removed in any alternative case, will gain some comfort when their child's sufferings are over. Finally, the resources of the hospital and the health system on the whole can be used in future with a greater benefit, than for extending the period of dying of the new-born infant, who's state can not be improved by the known methods of treatment. Surely, indirect and long-term consequences of the decision to refrain from antibiotic therapy must also be taken into account. Possibly, it can violate the public traditions of the society's especially protective attitude toward new-born infants. However, the risk of unfavourable consequences appears minimal. Therefore, in the discussed situation, the decision to refrain from antibiotic therapy and let the baby die, appears a morally justified action.

The same as every ethical theory, the theory of "action-utilitarianism" must be assessed from the perspective of its acceptability in accordance with two standards.

The critics of this theory assert that it contradicts our experience of moral life, in particular it ignores or does not justify the specific personal nature of human relationships and moral obligations. For example, we know that the parents' special moral obligation is to take care of their children. At the same time, from the perspective of the "action-utilitarianism" theory, redistribution of their energy and time and spending them on some other task could provide more benefit. In addition, the application of this theory does not sufficiently correspond to our moral conviction, that all individuals have certain rights. In some circumstances an action which provides maximal benefit (and, according to the theory, is morally right) violates some persons' rights according to the principle of "the purpose justifies the means". The theory claims excessively high moral demands to an individual, obliging him to estimate every action he makes from the perspective of achieving maximal benefit.

We can give a positive answer to the question, whether this theory provides effective guidance in solving ethical problems (this is the second criterion of a theory acceptability). The procedure of decision making is logical and clear, and the analysis of probable results of alternative actions helps to choose an option which will provide a maximal benefit. Although the theory in question corresponds to this standard well, its incomplete accordance with the first standard made the majority of modern utilitarians move from the "action-utilitarianism" theory to the "rule-utilitarianism" theory.

The "Rule-Utilitarianism" Theory. This theory is based on the following principle: people should act in accordance with rules, which provide the greatest prevalence of good over evil if followed in the majority of cases. In the general utilitarian theories the principle of benefit is the basic ethical principle. However, in contrast to the "action-utilitarianism" system, in which the determination of a morally rightful action depends on direct estimation of alternative actions in relation to the standard of benefit, in the "rule-utilitarianism" system the assessment of morality of one's actions presupposes indirect use of the principle of benefit. The followers of the "rule-utilitarianism" theory begin with developing a code of ethics in accordance with the principle of benefit. This includes the development of a set of meaningful moral rules by way of determining, which rules (as compared to possible alternatives), if followed in the majority of cases, provide the greatest prevalence of good over evil for everyone. In accordance with this theory, individual acts are morally right, if they correspond to these rules. The difference between the two types of utilitarianism is presented in a schematic form in figure 2. In the "action-utilitarianism" theory the ethical decision is made in one stage, whereas in the "rule-utilitarianism" theory it is made in two stages. The "action-utilitarianism" theory estimates an individual's action strictly on the basis of its benefit, this is why and this model is often named "extreme" or "unlimited" utilitarianism. The "rule-utilitarianism" theory develops the code of ethics as a set of moral rules based on the concept of benefit, and then estimates individual actions not on the basis of their practical results, but considering their accordance with the established set moral rules. This procedure explains the use of the term "limited utilitarianism".

In the "action-utilitarianism" theory moral rules occupy an inferior position. They simply present certain practical guidance. In the "rule-utilitarianism" theory moral rules have a considerably more fundamental status and theoretical supremacy. In the first approach a code of ethics can be established on the base of utility principles as "generally accepted rules of morality", such as "do not kill", "do not steal", "do not lie", "keep your promises", etc. From the perspective of the criterion of benefit, the consequences of accepting the rule "do not kill" are much better than the results of accepting the rule "kill, whenever you like". Adopting the last rule would bring the society over to anarchy. On the base of utilitarianism it is possible to adopt not only prohibitive rules but also ones of permissive nature. It is quite obvious that the society gains from including the following rules in the code of ethics: "help the people in need" or "do not let an innocent person be harmed". However, in the real life unreserved observation of all the moral rules may result in conflicts between them. Therefore, the code of ethics should contain justified exceptions. For example, the "rule-utilitaria-

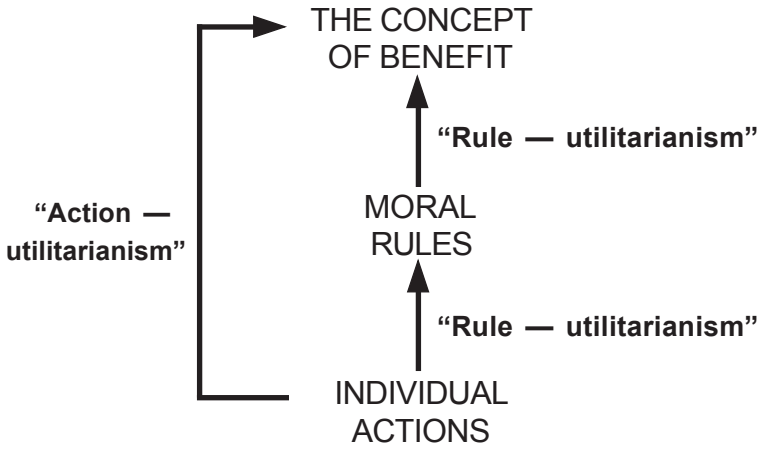

Fig. 2. Distinction beetween the types of utilitarianism

nism" theory considers killing with the purpose of self-defence a morally justified exception from the rule "do not kill". This exception is based on the fact that although the observation of the "do not kill" rule has incomparably better consequences, than "kill, whenever you like", the rule "do not kill, except for self-defence" provides the best balance of good and evil for everyone. In the same way, accepting the rule "do not lie, except for the necessity of protecting an innocent person against serious harm", preserves all the social benefits of adopting the rule "do not lie", but provides an additional social benefit by increasing the extent of personal safety for the potential victims of violence.

The use of the "rule-utilitarianism" theory in the biomedical context can be illustrated by the discussion of the question, whether a doctor has a right to lie to the patient, by telling him that his illness is not mortal, when in reality it is. From the perspective of the "rule-utilitarianism" theory this problem is conceptualised as the issue of possible justified exceptions from the rule "do not lie". By the way, from the positions of the "action-utilitarianism" theory, the problem should be solved in every individual case separately on the basis of the maximal benefit principle. Let us assume that the rule "do not lie" is supplemented by a specification: "except for the cases, when in a doctor's opinion it is be better for the patient not to know about the terminal nature of his disease". Will the acceptance of the rule, which contains such an exception, have better consequences than the same rule with no exceptions? The answer is disputable, but from the positions of the "action-utilitarianism" theory the offered exception is not justified. The acceptance of the rule with the offered exception would probably protect

many patients, at least from negative emotions aroused by the information about the mortality of their disease. However, on the other hand, this gain may turn out insignificant, because of the violation of trustful relations between the doctor and patient. The point is that if the patient's relatives fall ill in future, they will not trust a doctor's information concerning their disease. The question, whether a more limited exception from this rule can be formulated and accepted, remains open.

The "rule-utilitarianism" theory corresponds to the first criterion of ethical theories acceptability (co-ordination with our experience of moral life) to a greater extent than the "action-utilitarianism" theory. However, both these theories do not provide adequate theoretical grounds for human rights and social justice.

From the position of the second criterion of acceptability, the "rule-utilitarianism" theory can get a positive estimation, because it offers effective guidance in the solving of specific ethical problems. In the situations of dilemma, when one moral rule or principle leads us one way, and the other — drives us in the opposite direction, the "rule-utilitarianism" theory suggests to set a relative priority by analysing the consequences of adding possible exceptions to the conflicting rules. The dilemma is solved by accepting a rule, which would provide maximal benefit.

Theories based on similar principles. Theories based on the principles similar to the Kantian ethics and utilitarianism make an accent on the existence of obligations. The Kantian and utilitarianism theories are based on the principles of monism, when one absolute principle determines the nature of actions within the limits of the ethical system. In contrast to them, theories based on similar principles have pluralistic nature, when two or more conditional (non-absolute, *prima facie*) principles form the general level of normative assertions. The other distinguishing feature of the theories based on principles is their closeness to the generally accepted morals, they do not rely of pure reflection, natural laws, special moral sense, etc.

Theories based on principles are designed to find a way out of the "obligations conflict" situation, which requires opposite actions, although only one decision must be made. Such situations evoke feelings of vagueness and insolvability of the problem. A situation of "obligations conflict" can be solved neither from the position of utilitarianism, nor from the Kantian position, because monistic theories provide only a one-direction algorithm of decision-making. Utilitarians see the basis of different ethical obligations in the principle of achieving a maximal benefit. However, the assertion, that in real life there is only one obligation of enhancing the benefit does not comport with good ethical sense and with the fact that a vast number of different obligations toward different people exists. According to Kant's theory, our different obligations are defined by the categorical im-

perative. In the real life, though, the principle of absolute priority of direct obligations over the indirect ones is unacceptable.

The main theory based on principles is the *principalism* theory, formulated by T. Beauchamp and J. Childress (1979). It occupies an important place among the XX-th century dominant ethical theories. Principalism has much in common with Ross's theory (1930), in which the concept of "*prima facie*" obligations is suggested. In the translation from Latin this term means "*on the face value*". However, the expression "conditional" describes the nature of these obligations better. The list of conditional obligations was presented above. A conditional *prima facie* obligation, unlike an absolute one, can be inferior to another conditional obligation, which is more weighty in a specific situation. In principalism (same as in V. Ross's theory) there are no absolute (unconditional) obligations, and only conditional (*prima facie*) ones exist. Conditional obligations do not have a single basis and originate from numerous morally meaningful attitudes, such as a citizen's attitude toward the state, one man's — toward another, the parents' attitude to their child, a husband's — toward his wife, a creditor's attitude to the debtor, that of a person who gave a promise — toward the person whom this promise concernes, etc. Each of these attitudes is based on a certain conditional obligation: it exerts greater or smaller moral pressure depending on the circumstances of a concrete case. In non-problem situations, when we have only one conditional obligation, it is this obligation which is actual (real) for us. In the situation of obligations conflict, when two or more conditional obligations compete for priority, only one of them, more weighty under the existing circumstances, can become our actual (real) obligation. According to the principalism theory, an ethical problem can be adequately conceptualised, analysed and solved by its confrontation with the principles, each of which, corresponds to the conditional (*prima facie*) obligations. Four principles were formulated specially for the field of biomedical ethics: respect to autonomy, non-harming, help and support, and social justice. These principles originate from the principles of generally accepted morals. In decision-making it is necessary to take into account the relation of these principles to other aspects of our moral life, such as moral emotions, values and rights. In spite of inevitable hesitation, the decision must be built on the basis of moral justice. In the principalism theory there is neither a single uniting principle or conception, nor a description of the highest good. Every principle, on one hand, is related to a conditional obligation, and on the another — can be subjected to revision. Not a single principle operates as tyranny, they all presuppose possibility of compromise. In some difficult conflict situations a single correct decision may be absent, because two or more morally acceptable actions are in an inevitable conflict and are equivalent in these specific circumstances.

The analysis of active euthanasia ethical acceptability can serve as an example of "obligations conflict" solution. The conceptualisation of this problem consists in the conflict between the obligation to help and support on one hand, and the obligation not to harm — on the other. The conflicting obligations correspond to the main principles of the theory. Murder as such is absolutely morally unacceptable, it conflicts with the conditional (*prima facie*) obligation to cause no harm. On the other hand, ceasing the life of a terminally ill patient suffering from intensive pain can not be considered morally unacceptable in all cases, because in some situations it corresponds to the conditional (*prima facie*) obligation to help and support. Although murder is amoral from point of conditional (*prima facie*) obligation, it can be the only way of fulfilling other moral commitments. However, when conditional (*prima facie*) obligations are overcome or outweighed by other circumstances, they do not simply disappear or evaporate, they always leave moral marks, which are reflected in the agent's relations and further actions.

In the estimation of the principalism theory from the perspective of its ethical acceptability, we must traditionally use the two standard criteria mentioned above. We can assert that this theory comports with our experience of moral life well, because it is based on the "ordinary moral sense". At the same time, although principalism offers a useful model for our moral dilemmas conceptualisation, it does not provide reliable guidance for their solving. This situation can be characterized by D. Hume's paradoxical statement, that "the principles on which people build their moral judgements are always the same, but the conclusions which they draw often appear very different". When people come to different conclusions, their moral judgements also should be the subjected to analysis.

INDUCTIVE METHODS

The inductive method of solving ethical problems cardinally differs from the deductive approach. It suggests to begin ethical analysis with the factual study of a specific case details: people, circumstances and relationships, engaged in a concrete dilemma. From the perspective of this approach it is considered that experience and observation are more useful pre-conditions of ethical arguments, than philosophical principles and theories. The adherents of the inductive method assert that qualitative and quantitative methods of empiric investigation are also acceptable for the identification and analysis of ethical issues in health services organization and clinical medicine.

According to the inductive conception, the analysis should begin with the ethical estimation of the specific features of a case. The ability to respond to individual features enables one to understand what more general principles and obligations are most effective in a certain situation. The choice of ethical principles and obligations appropriate for a concrete ethical problem is an important stage of the inductive procedure. Finally, an attempt is made to compare general principles and obligations to the concrete facts and intuitional judgements, with no reference to any philosophical theory. For example, if a person imagines himself in a specific moral situation, this can help him understand the limits of general principles and obligations. It is more important for a person engaged in ethical analysis to try and imagine different prospects, or to understand what can be done in similar situations, than to remain impartial.

Unlike the deductive analysis, inductive approach inevitably preserves vagueness and remaining tension in ethical judgements. The movement from specific to general and then back to specific is connected not with logical operations, but rather with practical opinions. In the inductive analysis logical arguments serve as a support for the conclusion without its irrefutable logical proof. In other words, an inductive argument is supposed to make a certain conclusion more appropriate and probable, but does not make it logically inevitable. The inductive approach determines also, that general leading principles are not universally applicable, and calls to use general normative principles with the clear understanding of their benefits and limitations. In accordance with the inductive model, the core of ethical thought consists not in mastering philosophical theories, but in moral experience and estimation.

The algorithm of the inductive method of ethical analysis includes the followings stages:

1. Give attention to the specific features of the case.
2. Find appropriate ethical principles and obligations.
3. Balance concrete details and general principles.

In rare cases an additional fourth step is required to carry out objective balancing of private and general issues. It is needed, when the general principle or obligation engaged in the ethical analysis is questionable. This situation is possible, if a certain argument, on which the principle or obligation is based, is not considered reasonable any more, and its value became doubtful. Then the following actions are necessary:

4. Reject or modify the general ethical principle by identifying, on what unreasonable argument it is based.

The inductive model can co-ordinate interdisciplinary points of view. The multidisciplinary inductive model can unite under general principles not only positions, ensuing from philosophical theories, but also those, which

come from numerous disciplines and sources. The last can include life experience of direct observation of the impact, which ethical problems and their solving have on human relationships. The subject of history can also be included in the multidisciplinary inductive model, because many ethical problems have a long-term nature and are mentioned in historical sources. Even if a specific case is unusual, it can have important analogies with cases which had occurred in the past. Literature is another possible source of the common ethical understanding, because it analyses moral issues when describing different characters and life situations. Finally, different cultures also provide a valuable base of moral pre-conditions for ethical case analysis. The problem consists only in the fact, that the dominant culture in the society often represses the ethical views of other cultural groups, and the values of a separately taken culture can become a source of conclusions, which have a conflict nature in relation to other cultures of national minorities.

The variants of inductive approach to the ethical problems solving include the casuistic method, ethics of care, and feminist ethics.

The Casuistic Method. The casuistic method was developed by ancient thinkers and was widely used in the ethical discussions of Middle Ages. The assertion, that the deductive type of thought "from general to specific" is inadequate for solving concrete problems (such as the bioethical ones) became the theoretical pre-condition of the casuistic method. The revival of this method in the biomedical aspect was the merit of Jonsen and Toulmin (1988).

The adherents of the casuistic method proceed from the opinion, that none of the existent ethical systems can overcome distinctions between our moral ideas. This resulted in the absence of consensus in the estimation of ethical constructions. The casuistic method of ethical problems analysis is justified also by the fact, that our real moral thought usually lacks direct deductive constructions which ground ethical judgement on certain higher principles. Practical worldly wisdom requires to define, which norms, principles and rules are applicable to a concrete ethically difficult or ambivalent case. The followers of the casuistic method do not agree, that a practical question can be answered on the basis of Kantian, utilitarian or principalism theories. Ethical theories do not take into account the fact, that moral definiteness wherein it exists, concerns concrete cases.

The casuistic method is based on case analysis. It begins with clear "model" cases (paradigms), which are applicable to the analysed problem and specify correct actions or judgements. From such simple cases the rules and principles of conduct are extracted, for example, "stealing is amoral". "Model" cases (paradigms) help to illuminate the problems of other cases by the method of analogy. Rules of conduct and principles inferred

from the paradigms are compared with the actions which have ambivalent or conflict ethical basis. Sometimes they include assertions on the necessity of exceptions from the rules.

For the correct moral estimation of a specific case we should begin with defining appropriate "model" cases. Difficulties are inevitable, if the "model" cases are indefinite or ambiguous, or if two or more "model" cases point in conflicting directions. The history of moral practice consists of permanent clarification of the use of "model" cases (paradigms) and accepted exceptions from the rules.

Moral analysis of cases is impossible without reference to existing moral traditions. The casuistic method asserts priority of practice over theory. Moral norms should be set on the basis of practice, and practice must not be justified or reprobated by absolute moral principles, because they simply do not exist. The priority of practice to a great extent is a consequence of historical tradition as a permanent base of the European understanding of morality. The casuistic method is refreshed and developed also by the activity of different organizations, which analyse and summarize the real ethical practice of solving problems in separate occasion. The casuistic thought moves from a clear and obvious case to a more difficult and problematic one. It is based on the accordance of important principles to a certain case. The idea proceeds from this base to a moral judgement.

In everyday medical practice new cases which require urgent practical solving often appear. The followers of the casuistic method are sure that neither elegant theories nor critical questions give answers to arising clinical problems. They have a number of paradigms ("model" cases), for example those, which reflect ethics of managing the terminals patients, etc. These cases are clear and can be used in discussions with opponents. They contain careful analysis of opinions with the attained consensus and points of disagreement. Persuasion of listeners is achieved on the basis of paradigms, by comparing opinions and presenting analogies, which illustrate the best decision. In this sense the spirit of ancient philosophers-casuists discussions is present in the modern hospitals. This fact confirms the assertion that bioethics has rescued the normative ethics from death.

As an example of the casuistic method application, we can consider the question, whether the parents who belong to the Witnesses of Jehovah church have a right to forbid blood transfusion for their young children, who are at the risk of dieing without it. Instead of turning to the ethical theory or general principles, such as help and support or respect to autonomy, the casuistic method will be directed at the attempt of solving the problem by finding an analogy in cases, which do not involve serious differing in opinions. A follower of the casuistic method will present different paradigms ("model" cases), which firstly support the competent adults'

right to decline medical treatment offered to them, and secondly, the parents' right to make decisions for their children. Respecting the last right, the society, for instance, does not forbid parents to send their children to religious schools. On the other hand, the society tends to limit the parents' choice, which children causes serious harm. Proceeding from this, parents have complete freedom in the choice of school, to which they wish to send their child, but they do not have a right to deprive the child of the possibility to attend school in general (except for the cases of providing adequate education at home). The decision to decline all kinds of education would have a serious impact on the child's wellbeing. A follower of the casuistic method will use an analogy and will be able to assert that the parents have no right to decline blood transfusion for their child. Such a decision is amoral because it inflicts irreparable harm. The child unlike its parents, did not make an independent decision to become a member of the Witnesses of Jehovah church. When the child grows up, he/she will be able to accept or reject this system of values and make corresponding medical and other decisions.

The casuistic method is a real alternative to the dominant ethical theories and methodology of ethical thought "from general to specific". It offers a way which corresponds to the real process of ethical problem solving. Moreover, the casuistic method can result in a consensus even when people differ in opinions regarding ethical theories. At least, the adherents of this methodology are undoubtedly right that separate specific moral assertions are more definite than ethical theories.

The critics of the casuistic method point out that although it indeed is an alternative to a number of dominant deductive ethical theories, at the same time it is close enough to principalism. Indeed, if concrete moral judgements are more definite than a complete ethical theory, it does not follow that these judgements are more definite than a separate moral principle. In other words, there are no reasons to assert that judgements concerning specific cases are more definite than judgements concerning conditional (*prima facie*) principles or rules suitable for a specific situation.

Another critical objection consists in the assertion that this method is too "intuitional" in solving difficult ethical problems.

The analysis of strong and weak sides of the casuistic method results in the conclusion that it can be effectively applied as a component part of more modern models of ethical thought.

Ethics of care. This method focuses attention on the emotional component of moral life with a special accent on sympathy and concern for other people's needs, i.e. on care and support. Same as the casuistic method, ethics of care concentrates on the specific features and the situations of moral judgement.

The method strongly emphasizes the analysis of human relationships and responsibility for one's moral decision. The ethics of care was developed by C. Gilligan (1982) in the process of studying sexual distinctions in ethical thought. The investigations of reaction to moral conflicts show that women tend to concentrate on the details of human relationships and search innovative ways of problem solving, which maximally protect the interests of all interested persons. In contrast to them, men usually try to identify and apply suitable principles or rules, which they consider universal or valuable from the point of justice, even if somebody's interests are violated as a result. The first type of approach was named ethics of care (or responsibility), and the second, which includes deductive methods — ethics of justice. Surely, these empiric correlations are not absolute: the men's actions include elements of care, and women use principles of justice. Historically the traditional ethical approaches correspond to moral experience of men more than women. C. Gilligan comes to the conclusion, that there is no reason to believe that the ethics of care is less meaningful than the ethics of justice, and the ideal ethics should include both these approaches.

Ethics of care orients universal principles and rights in the direction of care, support, interpersonal relations and humane attitudes. The criticism of the deductive methods of ethical analysis is based on the doubt in the impartiality and justice as fundamental aspects of moral thought, which actually reflect only the masculine ethical thought. Partiality which originates from mutual relations of care is no less legitimate. Certain relationships are exceptionally important. For example, in many cases it is permissible for parents to place their children's interests higher than other children's. Moreover, abstract principles of traditional theories often have very limited practical application, and to solve ethical problems we need to pay attention to details and consider specific circumstances.

In many difficult situations of ethical conflict such principles as the Kantian categorical imperative or the utilitarian credo of "multiplying benefit to a greatest possible extent" simply give inadequate guidance. Moreover, ethical theories with abstract principles often ignore the emotional component of moral life. Display of care in accordance with other people's needs is often more morally preferable, than a remote, passionless moral estimation. For example, ethics of care firmly supports a doctor's cordial attitude toward every patient with no ethical estimation of its consequences (required by utilitarianism) or obligatory personal respect to him/her (presupposed by the Kantian theory). The abstract nature of deductive methods of ethical analysis limits the possibilities of considering the main features of moral experience in separate contingents of people: women, parents, representatives of minorities, or colleagues-professionals. A medical worker acting in the spirit ethics of care must find out a patient's individual physiological and

psychological needs and try satisfy them on the basis of individualized care and supervision. He must also try to establish, maintain and improve relations between all the interested persons: the patient, team of medical professionals and the patient's family.

The application of ethics of care in the analysis of bioethical problem can be illustrated by a case when a nurse is in a situation of conflict between her duties toward a patient and her duties toward a doctor as the leader of a medical specialists' team. The essence of the problem may consist in the nurse's opinion that the doctor does not use all modern treatment possibilities in this case. If we choose the approach of the "ethics of justice", the conceptualisation and solving of the problem will be carried out from the positions of universal benefit (utilitarianism) or hierarchy of duties (Kant's deontology). In contrast to them, the ethics of care focuses on the concrete relationships and responsibility effluent from them. The influence of possible scenarios on interpersonal relations is estimated, and the conflict is solved with the maximal observation of interests of all persons concerned, above all things — the patient's.

The Feminist Ethics. Feminist ethics proceeds from the recognition of the existence of specific female views upon morals, and in this aspect it is consonant with the ethics of care. This ethics requires consideration of the women's moral experience, although often supposes critically that their unequal position has substantial influence on the forming of this experience. Feminist ethics stresses the moral importance of overcoming all forms of oppression with a special accent on the discrimination of women. These features of feminist ethics determine the special moral attitude toward women and, what is very important — to other historically oppressed strata of population and minorities. The accent is made both on the value women's interests, and on the circumstances which especially affect them or have a negative impact on them. For instance, in bioethical discussions feminists study thoroughly the role of women in the decision-making concerning the cases of mother-foetus conflict; they also pay attention to women the almost exclusive members of trained nurses profession. The features of women's position in biomedical research, moral complications of substitute maternity, problems of *in vitro* fertilising and other disputable questions related to generic technologies are also discussed.

Special attention is given to overcoming all the oppression practices and institutes. Feminists consider that disproportionate engagement of women in the sphere of care provision may reflect their inferior position in the society. They stress that child education, care, attempts to save mutual relations at almost any cost, possibly, are signs of the oppressed groups and are characteristic not only of women but also of both genders in the groups of population, which were subjected to oppression or colonization. Radical

feminists assert also, that the maternity values which occupy a special place in the ethics of care, concern only traditional families, and are devalued in incomplete families, civil marriages, or among homosexuals. They consider also that taking care of others prevents women from satisfying their own needs in an adequate way on the basis of the autonomy principles and human rights.

ALTERNATIVE METHODS AND APPROACHES

Each of the described above deductive and inductive theories offers a construction which is used to determine which human actions are morally right, and which are morally wrong. One of the alternative approaches in the ethics science is the development of ethical theories, which are focused not on the action but on the human character on the whole. They try to give an answer to a wider question, concerning what is good and what bad. Such an alternative approach is reflected in the theory of virtuous ethics.

The Theory of Virtuous Ethics. In the traditional ethical theories focused on the moral estimation of human action sets of principles and rules are considered as the main basis of moral guidance. Sometimes these principles and rules are expressed in a language rights and duties. For example, rules can be formulated, saying that a competent adult has a right to decline suggested treatment, and a medical worker is obliged to respect a competent adult's decisions.

Virtuous ethics has another approach, and following traditions of Plato and Aristotle, it attaches basic significance to virtuous character. Virtuous ethics is focused on the *agent*, i.e. the person who performs an action, instead of the action itself. In the ethical theories based on the estimation of actions the main goal is to ground the moral correct action, whereas in the virtuous ethics the basic accent concerns the traits and qualities a person should possess. In the bioethical context virtue can be defined as a morally valuable character trait. Virtues include such features of human personality, as justice, prudence, frugality, bravery, veracity, sincerity, and compassion. Faith, hope and love are theological (Christian) virtues.

During the last decades we can observe the growth of virtuous ethics influence and the development of emotional aspects in bioethics. Several authors try to prove the necessity to renounce ethical theories, based on the estimation of actions, and develop virtuous ethics or, at least, to reach their equal in rights coexistence. The advantage of the virtuous ethics can be

proved by the fact that we often morally estimate the agents' motivation and character, rather than just their actions. Sometimes we reprove a person who had acted correctly, but on the basis of doubtful motivation or approach. At the same time, we often do not censure a person for acting incorrectly, if the action was performed on the base of noble motivation and virtuous traits. Virtuous ethics not only corresponds to our moral life experience but also is a good guidance for moral dilemmas solving. In the opinion of the supporters of this alternative approach, virtuous ethics provides a more reliable basis for practical morally correct actions than principles, rules or codes. Virtuous traits must be formed in people by the society through education and cultivation of correct models of conduct. In many cases it is impossible to ground the rightness of an action without reference to virtue. Moreover, the mode and quality of our actions (from the perspective of their moral characteristics) are often no less (and sometimes even more) important than the actions themselves.

At present the conception of both alternative approaches combination is most acknowledged in the ethical analysis. It is based on the recognition of a number of facts. Firstly, neither the ethical guidance in accordance with principles and rules, nor the ethical guidance in accordance with virtues exhaust all the plenitude of our moral life. A person can possess a pleasant character and correct motivation, but act wrongly. On the other hand, actions which have nothing to do with virtues, are not always wrong. In our life we estimate both the actions and the nature of the moral position. Besides, the rules, principles and codes of ethical theories, based on actions (such as requirements of informed consent to medical treatment, of confidentiality, veracity and others) often help to establish correct mutual relations between the team of medical professionals, patients and their family members, in which certain virtues can be easier realized. We should also take into account that the specification of virtues is not always a sufficient ethical guidance to practical activity. In bioethics we are often confronted with specific questions, for instance, whether a doctor has a right to violate confidentiality and if yes, in what situation. It is impossible to answer such questions with isolated reference to virtue.

A situation, related to a doctor's moral choice after he has diagnosed an oncological disease in a patient can illustrate the application of virtuous ethics in the biomedical context. He is obliged to give the patient some information about the results of his investigation. At the same time, having made an individual assessment of the situation, he realizes that such principles as help, support and avoiding harm are too general to help him in this concrete case. The doctor can turn to the ideas of compassion, sympathy and sincerity. Although these concepts describe virtues, we can formulate certain rules of action on their basis: "express compassion", "express your

sympathy", "be sincere". This means that in a concrete situation the doctor, in order to solve the ethical dilemma, should be sympathetic, compassionate and sincere with his patient (naturally, there is no established set of rules, saying how to carry this out). In other words, a doctor should show virtue and morality. This can be carried out by modelling his conduct according to his teacher's example, or to his respected colleague's behaviour, if he identifies them as possessing the necessary traits.

The Theory of "Reflective Equilibrium". The *reflective equilibrium* theory was developed by J. Rawls (1971) as an alternative approach in relation to the deductive and inductive methods of ethical analysis. The necessity of alternative theories is conditioned by the absence of any method's exclusive status. The modern stage of the bioethical thought development is characterized by the assertion, that a combination of deductive and inductive methods offers a third model of ethical analysis. The deductive method provides a decision-making procedure "from general to specific", in which philosophical theories and ethical principles are premises, and conclusions present concrete logical answers to specific moral dilemmas.

In contrast to this procedure, the inductive methods offer the algorithm of problem solving "from specific to general", proceeding from the careful estimation of a concrete case specific features and finding support in general philosophical theories and principles, and also in other disciplines and sources. Unlike obviousness and definiteness of the deductive method, the inductive approach does not present one or other conclusion as logically necessary. Each of these models is excessively rigid in the determination of the level of ethics persuasiveness priority: theories and principles, or concrete cases. Presumably, our ethical essence and thought can not be understood on the exclusive basis of any single approach.

In accordance with J. Rawls' model of *reflective equilibrium* no level of ethical persuasiveness should possess priority. Legitimacy can be set at all the levels of ethical analysis: 1) theories; 2) principles and rules of different extents of specificity; and 3) judgements in relation to cases. Judgements of any level, which seem especially convincing, can be used for the revision of less definite judgements of any other level.

The theory of reflective equilibrium suggests to begin the analysis with weighted judgements, in relation to which a high extent of trust was attained after careful and intensive discussion. The weighted judgements can concern any level of ethical analysis. Some of them, as in the casuistic method, can be judgements on specific cases; others may be rules (for example, the prohibition of violence), or principles (for example, respect toward autonomy). Only unprejudiced judgement are considered weighted. The weighted judgements serve as a basis for revising other ethical beliefs and views with the purpose of achieving a coherent aggregate of moral

estimations. The coherency of the ethical analysis (the term *coherentism* is often used in this context) is provided by implementing a possibly greater number of trustworthy theories, principles and approaches in the estimation of a practical problem. The coherent ethical analysis should move in both directions: from general to specific ("from top to bottom"), and from specific to general ("from bottom to top") with the use of both deductive and inductive methods, and also alternative approaches (for example, virtuous ethics).

The theory of reflective equilibrium, including its call for the coherency of the ethical analysis, is an important support of traditional approaches. The model includes both principles of the casuistic method, and the argumentation of principalism. It permits the use of deductivism as a theoretical method if it is necessary to verify our particular propositions. Depending on the course which the ethical analysis takes, the model can also include elements of the virtuous theory, the ethics of care and the feminist ethics. In this connection, R. M. Veatch (2003) considers the theory of reflective equilibrium as a "complete theory of bioethics". On the whole, it can provide flexible and balanced approach to moral thought.

The application of the reflective equilibrium theory is directed at the revision of less convincing judgements of any level from the position of weighted judgements with the purpose of achieving maximal cohesion of all the system of ethical beliefs and solving conflicts on this basis.

The revision of judgements can be carried out "from top to bottom", i.e. from general principles to a concrete case. For example, as a group of participants of an important medical research is selected, a question can arise about the expedience of giving them full information on the essence of the planned experiment, because this can result in diminishing of the number of examinees. The revision of this ethical judgement can begin with Kant's principle of categorical imperative concerning the amorality of treating a human being exceptionally as the means of reaching some goal. The selected participants of the research will not be also a goal, if they don't give an informed consent to medical research. This example illustrates the movement of ethical thought from a principle to a concrete case, but according to the theory of reflective equilibrium an opposite orientation of ethical judgements revision is possible too. For example, if a psychiatrist learns that his patient intends to cause harm to a third person, a weighted judgement concerning the necessity of this person's defence is adopted at the level of case analysis and makes the psychiatrist revise the principle of confidentiality and make an exception in this clinical situation.

The question of the method we use to define judgements or norms which must be revised in a conflict situation is practically important. How can we justify every concrete solution of a conflict? It is important to re-

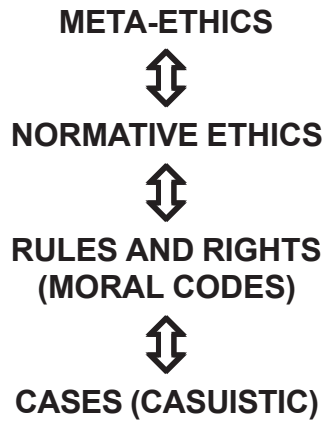

Fig. 3. The levels of moral reasoning

solve an ethical conflict by such revision of judgements, which would provide the best coherence of the analyst's ethical views.

R. M. Veatch (2003) examines four levels of moral grounds in the reflective equilibrium, adding the fourth level to the ones discussed above — it is meta-ethics (fig. 3). Complete and comprehensive approach to bioethics is provided by the creation of "equilibrium" of all four levels. The exact place where we begin the analysis is not principally important. For example, we can begin with the analysis of a concrete case, and if the casuistic approach does not help to resolve the conflict, we can resort to making a weighted judgement at some other level, to make the revision of our ethical views either at the level of a concrete case or at a higher level. Pointers in figure 3 show possible movement of thought in both directions of moral grounding.

Very often in biomedical ethics the discussion begins at the level of an individual concrete case. Usually the ethically correct decision is obvious and it is often made intuitionally, automatically on the basis of deep-rooted moral views, and the medical worker may even not be aware of the fact of decision-making. Sometimes, though, the choice is more difficult and requires careful conscious estimation. A doctor can consult his colleagues or the members of the medical institution ethical committee. A patient can turn for help to his friends, relatives, religious and public organizations. As a result, information, containing experience of other clinical cases, which appear similar and were successfully solved in the past, can be obtained. Sometimes biblical stories, historical or legal cases, in regard to which the society came to consent, are used as analogies. Such cases are named "exemplary" or "model" cases. The majority of people agree that from the point of ethics similar cases should be considered identically. In fact, the main characteristic of an ethical judgement (unlike an ordinary taste or preference) is the confidence, that if substantial features are alike, the consideration of cases should be similar. If people can approve of what was done in a "model" case, and find that the new case is similar to the "model" one in its substantial features, they will be able to solve their ethics problems.

The next level of moral reasoning are rules and rights (codes of ethics). We can proceed to them, if the basic ethical judgements at the casuistic level do not solve the problem, or if it is impossible to agree with the ethical solution of the "model" case, or if we consider that the examined problem does not coincide with the "model" case in substantial features. Sometimes an ethics code can explain what is legal or ethical. Not all the lawful actions are at the same time moral, and not all illegal actions are necessarily unethical. If a rule or a right are considered ethical, this means that they are based on the moral system, which is the primary system of beliefs and norms concerning the rightness or wrongness of actions or human character traits. We can use different codes and statutes, containing rules of civil, cultural, political, or religious organizations, documents of medical professional associations and postulates of different theories. Assertions like: "a surgeon must always receive the patient's consent before an operation", or "the medical information about a patient must be confidential" are examples of rules. The same assertions can be expressed not as rules, but as rights: "a patient has a right to declare his/her consent before an operation", or "a patient has a right to the confidentiality of the medical information which concerns him/her". Such assertions are named *reciprocal*, they are specific and in combination with a number of other statements can answer the majority of basic bioethical problems in the medical practice. If the consent in regard to the rules applicability in the concrete case is reached, the ethical problem is solved at the second level.

One of the ethical contradictions is expressed in the discussion as to how strictly the postulates, rules and rights should be observed. An extreme point of view (which is practically impossible to follow), is the so-called *legalism*. It asserts that there should be absolutely no exceptions from rules and rights. The opposite extreme is the opinion that every case is unique, so it is impossible to use any rules or rights for the estimation of people's behaviour. This approach is called *antinomianism* and it is also unsuitable for practical application. Two intermediate points of view are more acceptable. *Situationalism* considers moral rules simply as "guidelines", "practical recommendations", which can be used in every concrete situation variously. And, finally, the point of view named "*practical rules*" orients people at strict observation of rules, which establish a certain order. Exceptions are possible only in extraordinary situations, they are made much rarer than by the followers of situationalism.

In cases when the application of different rules or rights does not help to overcome contradictions, more thorough ethical analysis may be required. With this aim in view we can pass on to the third level of moral reasoning — the theories of normative ethics. It is at this level that the norms of behaviour and character traits are discussed. These basic norms allow to

formulate and protect the rules and rights. Universality and a wide range of application are the key signs of ethical norms. Normative ethics examines three types of questions, which the theory of actions, the theory of values and the theory of virtuousness answer.

The theory of action answers the question what principles make an action morally correct. The answer includes a list of moral principles, such as help and support, non-harming, respect toward autonomy, justice and others. On the whole, principles of correct action are usually subdivided into ones which promote the best consequences, and ones based on duties. Considering that bioethics includes more than one ethical principle, the theory of actions, as a part of normative ethics, must be able to answer the question, how to solve conflicts between them.

The theory of values contains an answer to the question addressed to the normative ethics: "What consequences of an action should be considered good or valuable?" In biomedical ethics help and support (i.e. creating good consequences) is the first principle of correct actions, and non-harming (i.e. preventing bad consequences) is the second principle of correct actions. There are different opinions as to what should be considered ethically valuable. Some things, money, for example, seem valuable, but in fact they are only instrumental, because they can only help in getting something which has veritable intrinsic value. Standard answers to the question what possesses an intrinsic value include happiness, beauty, knowledge, truth, morals, kindness and, what is most important for biomedical ethics, — health.

The theory of virtuousness gives an answer to the third question of normative ethics: "What character traits deserve praise?". Moral qualities which deserve approval, such as sympathy, goodwill, and loyalty are usually designated as virtues, this explains the name of this part of normative ethics — virtuous ethics. It is important that virtues should be correlated not with the nature of actions but with the character of the person who carries out these actions. We should distinguish the concepts of virtuousness and benefaction. Goodwill is a virtue, it is understood as a desire to do good. Benefaction (help and support) is a principle of correct action, which creates the best consequences. Sometimes a man wishes to do good, i.e. demonstrates the virtue of goodwill, but does not do good in the end, i.e. does not accomplish benefaction. Another person, unfriendly by nature, can accomplish benefaction, probably considering that in this case the promotion of the best consequences corresponds to his interests.

Thus, normative ethics supports ethical principles (theory of action), internal good (theory of values) and positive character traits (theory of virtuousness). Depending on the nature of the ethical problem and situation, we can take an interest in one of the questions more than in others.

For example, in 1970-s and 1980-s the specialists on bioethics concentrated on the principles of correct action. The theorists tried to understand whether a doctor acts morally rightly, if he aims at creating the best consequences, but hinders the movement toward autonomy or is not truthful enough. At that period a doctor's character was not in the centre of attention. It was important that his actions were morally correct, and nobody cared too much whether a doctor had a virtuous character. The bioethics, who at that time criticized the trend of medical paternalism, asserted that a virtuous doctor-paternalist acted in a morally wrong way by violating the principle of autonomy, even if he did it according to his best motives. Only at the beginning of 1990-s biomedical ethics returned to the more traditional interest to the virtues of a medical worker's character. Thereafter the establishment of balance between the ethical analysis of actions and the analysis of their performers' character began.

Sometimes in the process of moral grounding of ethical problem solving at the third level people find out what principles of correct action, or virtues, or intrinsic values, are most essential. For example, the participants of a discussion can agree that the principle of respect toward autonomy (or the principle of benefaction) is dominant, and solve the problem on this basis, after defining what moral rules or rights are legitimate in this specific situation. In more difficult cases the disagreement remains unsolved, and the participants of discussion can not come to a common opinion, what principles should predominate. For example, some participants of discussion may give the priority to the principle of benefaction, while others insist that the principle of autonomy is preferable, even if the respect toward autonomy will lead to worse consequences, i.e. will be less beneficent.

In other cases the participants of a discussion can fail to form a common judgement as to which principle is more important — the principle of correct action or character virtuousness. All such cases of prolonged discussion are grounds for carrying the moral reasoning to the last, fourth level — the level of meta-ethics.

Meta-ethics is directed at solving the principal ethical problem: the definition and interpretation of ethical terms. Meta-ethics examines the sources of ethics (i.e. how people know what principles or virtues are important), and the bases of ethics (i.e. how people know what is ethical). The level of meta-ethics does not consider the questions, which actions are morally correct, or what character traits are morally meaningful. It examines more fundamental problems: how can we get answers to these questions and how do we know that these answers are right.

Religious ethics has standard answers to these meta-ethical questions. For a believing man the determination of an act as correct, means that it is carried out in accordance with the divine will or according to the laws set

by God. If we tell a believer that a character trait is virtuous, this means to him that it is morally justified by God. Religious people are confident, that they know exactly what is ethical from such sources as the revelations, religious books, church traditions and authorities, and the religious and spiritual experience.

People who don't have religious faith adhere to different views. From their perspective natural laws and agreements between people can serve as universal bases of ethics. Traditional secular ethics shares the monotheistic religions opinion as to the universality of ethics. It considers that in a concrete ethical case all people should come to the same ethical judgement as to the rightness of the agent's conduct. The universalists certainly admit that in reality not all people will accede to a common judgement, but suppose that certain standards exist (such as divine will and law, or natural laws), in relation to which ethical judgements are collated.

Other secular theories share the opinion of polytheistic religions, that more than one standard of moral views exists. This meta-ethical position is named *relativism*, because it examines moral judgements in relation to a great number of standards and authorities. For example, for a polytheistic religion follower different cultures have the right to make different moral estimations. In one culture it is possible to justify active euthanasia of a suffering terminal patient from the religious position, while in another culture the same action is forbidden by religious authorities. In the same way secular ethics can also be relativistic, if it approves the standard of moral views estimation from the positions of specific cultures.

Meta-ethics considers the question as to how we learn what is ethical in different ways from religious and secular perspectives. Religious ethics believes that ethical views depend on the divine will or God's laws and we learn them from the holy scripture, revelations or church traditions. The secular ethics sees the basis of such knowledge in empiric experience. According to E. Kant, the knowledge about ethics is based on reason, and according to Hume — on experience of liking.

The meta-ethical issues are beyond the limits of everyday problems of bioethics. Fortunately, even if there are serious divergences at this level of ethical reasoning and it is impossible to achieve consent on the religious or secular basis, rapprochement of positions and consensus are possible at the three lower levels of moral reasoning. The participants of discussion can find consent in the issues of principles, virtues and intrinsic values of normative ethics. They can consent to many moral rules and rights. Sometimes it is possible to agree as to what should be considered morally correct in a concrete case, even if the consent at the meta-ethical level was not achieved. Views which are usually named the generally accepted moral, allow to attain consent in the majority of ethical dilemmas regardless of

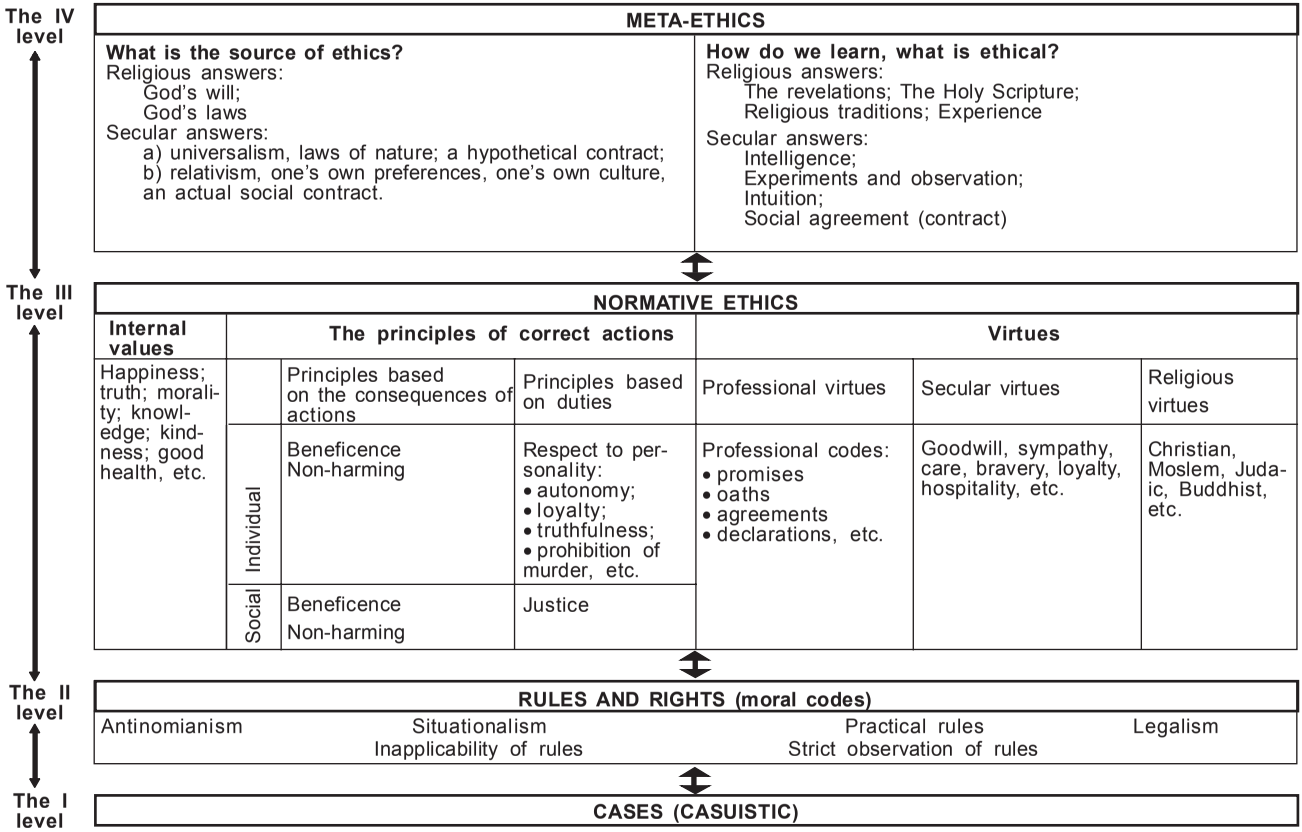

Fig. 4. The algorithm of moving from one level of ethical reasoning to another

culture, religion, policy or time. Usually reasonable people can come to mutual understanding at the lower levels of moral discussion. The algorithm of mental movement across the levels of ethical reasoning is presented in fig. 4.

The negative sides of the reflective equilibrium model include the lack of definiteness and insufficient structuring, which were the price for the attained flexibility and freedom from dogmatism. Deductivism, which identifies one unique principle as the basis for the ethical reasoning, offers a system or a method, which provides easier conceptualisation of problems. The casuistic method, due to its focusing on a concrete case, gives a clearer approach to the problem solving. A critic of the reflective equilibrium conception can declare that its followers do not know exactly at what level of ethical reasoning they should start and how to move across the levels. In theory, we should begin wherein the declaration of a well grounded judgement is possible. In practice we can begin simply where there is ethical interest and use all mechanisms of argumentation to achieve the most consistent ethical system of beliefs.

Section III

BIOMEDICAL ETHICS OF DOCTOR AND PATIENT RELATIONSHIPS

"A doctor's strength is in his heart."
Paracelsus

BIOETHICAL BASES OF A DOCTOR'S PROFESSIONAL ACTIVITY

In the bioethical bases of a doctor's professional activity we can single out a number of principles, such as: "do not harm", "do good", the principle of respect toward a patient's autonomy, and the principle of justice. The principles of confidentiality, truthfulness and informed consent are derivates of the above mentioned principles.

The principles of modern bioethics have originated long before the period of this science forming: some of them are related to the school of Hippocrates (IV-th century B.C.) and were formulated in the famous Hippocratic Oath. The Oath consists of two sections: dedication and the code of ethical conduct (Supplement 1).

In the section of dedication the doctor swears by Apollo, Asclepius and Hygieia and Panaceia and all the gods and goddesses, making them his witnesses that he will fulfil according to his ability and judgment this oath and this stipulation. The same section contains an obligation to honour his teacher and respect the corporate interests.

The second part of the Hippocratic Oath contains the ethical code, which regulates a doctor's professional activity in the field of dietetics, pharmacological therapy and surgery. The Oath includes a number of prohibitions, in particular the prohibition of abortions and euthanasia. In Hippocrates' traditions an accent was made on the special knowledge, training and experience of a medical worker, which had to be directly applied in the process of treatment. In accordance with this approach a doctor gives advice, and a conscientious patient follows this advice, because he knows that the educated and experienced specialist does his best in the patient's interests. In obedience to Hippocrates' traditions a doctor promises: "I will follow that

system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous". In the language of modern bioethics the application of every method "to the patient's benefit" makes the principle of help and support. "Abstaining from whatever is deleterious and mischievous" corresponds to the modern principle of "non-harming". The principles of help and support and non-harming taken together in the modern bioethics are considered as the principles of maximum: a doctor is obliged not only to "do good" and "keep the patients from harm", but to promote the greatest good possible and abstain from the slightest harm.

For a long period the doctors applied the text of the Hippocratic Oath as generalized moral wisdom. Some modern professional ethical codes adhere to the Hippocratic traditions at least in the sense, that they confirm that a doctor's duty consists in rendering help and support and keeping the patients from harm. The well known Declaration of Geneva (1948) is the most vivid example of such a code, named "The XX-th century Hippocratic Oath". It is cited in Supplement 2 in the 1983 edition. The Declaration of Geneva was adopted by the World Medical Association after World War II as a reaction of the national medical associations concord to medical experiments on people carried out in Nazi relocations centres. The Declaration is written in modern language, the appeals to ancient gods, prohibition of abortion and surgical limitations were excluded from its text. However, it contains the key position of the Hippocratic tradition: "the health of my patient will be my first consideration". In 1949 the 3th General Assembly of the World Medical Association had approved the International Code of Medical Ethics, the text of which is presented in Supplement 3 in the 1983 edition.

It is interesting that in half of the USA and Canada higher medical educational institutions the graduating students swear one of the versions of the Hippocratic Oath, and in one of them the original version of the Oath is pronounced. The modern "Solemn Oath of the Russian Doctor" was written according to the traditions of Hippocrates. The text of the oath sworn by the graduating students of the Ukrainian higher medical educational institutions is presented in Supplement 4.

The Hippocratic traditions, which express the principles of help and support and non-harming, have occupied the dominant position in the period of bioethics development and preserve their influence in the modern situation.

The principle of abstaining from harm is the eldest in the medical ethics. In its Latin formulation it sounds as follows: *primum non nocere*, which is translated as "foremost do not harm", and the word "foremost" can be interpreted in the sense that this principle is most essential in every doctor's

activity. Quite often the principle of *keeping from harm* is considered the core of Hippocrates' medical ethics. Every doctor will probably agree to W. Lambert's statement that "there are patients who can not be helped, but there are none who can not be harmed". We know that at times treatment can be harder and more painful than illness. We mean the side effects of medication, negative effects of simultaneous application of a large number of drugs, or the disparity between the expected benefit and possible risk of a medical interference.

From the ethical and legal points, inadmissible harm can be caused by:

1. Inaction, refusing to render help to a patient who needs it;
2. Lack of conscientiousness, evil or mercenary motives; and
3. Incorrect, improvident or unskilled actions.

The principle of "*doing good*" is a supplement and continuation of the previous one. Unlike the first principle it is not a prohibition but a norm which requires positive actions. Its sense is sometimes expressed in such words, as benefaction, charity, mercy, or philanthropy.

This principle presupposes not only avoidance of harm but active operating with the aim of its prevention and correction. This includes not only intended or unintended harm causal by a doctor, but also any harm which a doctor can prevent or correct, be it a patient's pain, suffering, inability or, finally, death. There are difficulties in the understanding and grounding of the principle of "doing good". For instance, in its extreme form it could be interpreted in the sense of obligatory self-sacrifice. Acting in accordance with this principle, one could consider himself obliged to offer his kidney or even both kidneys for transplantation to any person, even a stranger, otherwise speaking, to sacrifice his own life. But, obviously, it would be unreasonable and even immoral to require such a degree of self-sacrifice of a person. Therefore sometimes the principle of "doing good" should be understood as a moral ideal, but not a moral obligation: although following it deserves approval, but at the same time we should not consider amoral and reprobate a person who refuses to be actively beneficent to others.

Generally speaking, it is hard to imagine a separate doctor, and moreover all the system of health services and medicine, which would be limited only to the task of not harming the patients. In this case the society would simply have no reasons to support this system. Thus, the goal of all the health system consists not simply in abstaining from harm, but in providing the patients' wellbeing, and thus helping all the people and the society on the whole. For example, when the methods of preventing such illnesses as smallpox or plague were invented, realization of positive measures against them became natural, i.e. special programs of prophylaxis of these dangerous diseases were actively carried out at the national level. It would be morally irresponsible to abstain from taking these measures. The good which

the doctors and other medical professionals should pursue consists in promoting good health of their patients. The task of the health services is to prevent the loss of health if possible, or to recover a patient's health, if there is a reasonable hope for his recovery. In a number of cases the doctors have to be satisfied with less radical results, for example, with halting the progress of a developing disease, or — in the case of palliative medicine — with alleviating a dying patient's pain and sufferings.

In the traditions of Hippocrates the principles of "doing good" and "non-harming" were realized in the course of medical paternalism. During a historically protracted period of time paternalism was justified, but since 1960-s it was subjected to scalene criticism, because the nature of doctor and patient relations had changed. Firstly, the interpersonal co-operation between them weakened in the course of the medical science complication, growth of medical knowledge and perfection of medical technologies. Secondly, the increase of the rate of iatrogenic diseases, caused by medical interferences generated doubt in the infallibility of the doctors' knowledge and actions. Thirdly, suspicions arose that many doctors are engaged in practices, which violate the patients' interests and serve the interests of medical workers, pharmaceutical firms, insurance companies and state medical programs instead.

The change of the attitude toward doctors in the post-industrial society caused discussions, directed against excessive paternalism of the traditional codes of medical ethics. Many authors expressed moral opposition to the professional codes which support paternalistic opinions in the medical practice. For example, the morality of lies told for a patient's good was called in question as a practice which violates the patient's right to autonomy. Not only the patients but also medical workers, authorities, philosophers, and medical sociologists, began to cast doubt as to the doctors' right to make medical decisions on behalf of the patients. This orientation of discussion was promoted by anti-paternalistic community spirits, supported by the movements for civil laws, against the war in Vietnam, and for the women's rights. The doctors' priority in determination of what is harm or benefit for a patient was called in question. The critics of the Hippocratic ethics pointed out that in the Hippocratic Oath there were no clauses as to receiving a patient's informed consent to treatment. They drew attention to possible conflicts between the principle of "doing good" and other moral obligations, including the respect of a patient's autonomy. And, finally, the traditions of Hippocrates are challenged when there is a conflict between a patient's interests and the interests of other people. The Hippocratic Oath, at least in its original form, is focused exceptionally on an individual patient and does not take into account the interests of other citizens of the society in the fields of research medicine, the organization of health services, and in social justice.

As a result of these challenges new oaths and medical ethical codes appeared, which were based on other than Hippocratic traditions, and some of them had non-professional ethical systems at their background. The most important of these documents is 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 (the Council of Europe, Oviedo, 04.IV.1997) (Supplement 5).

The development and introduction of new ethical approaches took place in late 1960-s, in the situation when the newest achievements of biomedical science and practice created principally new clinical situations. Artificial ventilation of lights and other sustenance technologies not always rendered positive results. Even when the use of such interferences as kidney dialysis or pneumo-cardial resuscitation yielded brilliant direct results, remote outcomes remained indefinite. There was the atmosphere of some informative opposition, lunges and prosecutions in relation to medicine, the biomedical science, doctors and research workers. As a result, both patients and medical workers began to feel less comfortable than before, when doctors were in the position to decide independently whether to use a certain medical procedure or not. The public had certain "alerts", it developed a feeling that the newest biomedical technologies were risky and could cause unavoidable negative consequences, still unknown to the doctors and scientists. The level of the people's medical awareness and knowledge about the state of their health and about the nature of the recommended treatment grew. As a result they did not follow the specialists' advice automatically any more, often tried to find out the alternative points of view, and required more detailed information on the possibilities and features of the proposed treatment.

In 1960-s and 1970-s the practice of informed consent to medical interferences and to people's participation in medical research became an object of judicial consideration. Despite some doctors' opinion that complete disclosure of all medical information and getting the patients' informed consent were incompatible with skilled clinical practice, the requirement as to the necessity of granting the patients full information about every fact, which could be material for conscious decision, legally prevailed.

The consolidation and wide spreading of the conception of informed consent was partly related to the noticeable role of the principle of the *patients' autonomy* in the bioethical analysis. This principle presupposed respect to the choice made by a competent patient. In other words, people should be self-guided and self-determined whenever this is possible. In this connection medical professionals should not oppose to the wishes of a competent patient, even if the fulfilment of these wishes exposes the patient to danger. The respect of a patient's autonomy may result in the failure to observe the ethical principles of help and support or non-harming. Thus, in the conflict with other principles of bioethics autonomy scored an advan-

tage. This central position of the principle of autonomy in the early period of bioethics development was consolidated on the basis of debates as to the ethical problems of clinical tests and principle importance of getting the human examinee's voluntarily consent. In addition, the attention to the problem of the patient's choice of therapeutic methods was stimulated by the public concern about the doctors' paternalism in their relations with the patients. Only an autonomous person can make a voluntary choice, and only wherein there is such a choice it is possible to talk about responsibility and conscious application of ethical categories. The action can be considered autonomous only if the person who carries it out acts:

a) intentionally, i.e. in accordance with his/her own plan;

b) with precise understanding of what he/she is doing;

c) without external influence which would determine the course and result of his/her action.

According to the first condition, a purely automatic action, which we carry out without reflection, even if we understand its sense, should not be considered autonomous. The second and third conditions may be realized to a different degree in every case. If a doctor suggests a patient some serious surgical operation, it is quite unnecessary for the patient to have all the special knowledge about it which the doctor has. Generally speaking, to make an autonomous choice the patient needs to understand only the main things, and not all the small details involved in this situation. He can turn to his relations or friends for advice, and their opinions will surely influence his choice. But if he perceives this advice not as an order, but as additional information for decision-making, his final choice will be autonomous. In the end the patient can consent or disagree, accept or reject the doctor's suggestion. If he consents, he in fact authorizes the doctor's intention, i.e. makes it his own decision, — and thus the first condition of autonomous choice is observed.

It is quite possible that taking his choice, the patient will count on the doctor's authority above all things. However, even in this situation the choice which the patient makes is undoubtedly his own, and thus, autonomous decision. The principle of respect toward autonomy is based on the idea that a human personality is self-valuable regardless of all attendant circumstances. The principle of autonomy grants every person's right to non-interference with his/her plans and actions and, accordingly, it asserts other people's duty not to limit the person's autonomous actions. It certainly does not follow from this that people never have a right to hinder someone's autonomous actions. What is important here, is that in every case the limitation of autonomy must be specially grounded on other principles. It's not the point that this principle must never and under no circumstances be violated. It is important for a doctor to be morally aware of the reason, why

he has to limit a patient's autonomy. And if in a concrete situation the requirements of the principle of respect toward a patient's autonomy contradict to the requirements of some other principle, for example, the principle of non-harming, one of them will be violated. A typical example of such a situation is the case of informing an incurable patient about the diagnosis of his disease. The revealing of the true information in this case can do him irreparable harm and undermine his psychical and moral powers. Therefore, if the patient does not ask the question about his diagnosis, the doctor may refrain from giving him the information, although such an action will violate the principle of respect toward the patient's autonomy. We should point out that the legislation of many countries grants the patients a right to know their diagnoses, although the laws usually add that the information should be reported "in a delicate form".

It should be noted that the action of the principle of respect toward autonomy is naturally limited in regard to people who are unable to operate autonomously — children under the age of 15 years, patients with mental disorders, people in the state of alcohol or narcotic intoxication, etc. It is important here that the limitation of autonomy is justified by the principle of "doing good", i.e. other people act with the purpose of protecting this person from the harm he can cause to himself.

As a result of the consolidation and expansion of the principle of the patients' autonomy in 1960-s–1970-s a doctor's role changed substantially. He began to operate as a kind of "servant", whom the patients invite when they consider it necessary. To an ever increasing extent doctors, as well as other professionals, turned into the service staff, which is near at hand and always at the patients' disposal. In accordance with this approach the relationship between the patients and medical workers followed the model of contract relationships which exist in other regions, for example in jurisprudence or business. Like a lawyer or an accountant, a doctor gives his clients full information, which they need to make an informed choice of treatment. In its extreme forms this model is sometimes named "scientific", "engineering" or "informative", when a medical worker's responsibility consists simply in granting the patient complete information on what is best for him from the doctor's point of view. In this situation the patient's informed consent to treatment becomes a decisive test in the estimation of the ethical attitude toward the patient.

Today the necessity of adjusting the central position of the principle of a patient's autonomy in bioethics became obvious, this need is conditioned by a number of circumstances.

Firstly, a patient's autonomy and his ability to make independent decisions can be limited by the disease. When a person is ill, he/she is irritable, low-spirited and disturbed, and their judgements sometimes substantially differ from those which are characteristic of them when they are healthy.

Secondly, sometimes the duty to respect a patient's autonomy can result in the violation of the medical worker's own autonomy, when he/she is suggested to act against his/her human or professional values.

Thirdly, the observance of a patient's autonomy can sometimes conflict with a doctor's responsibility in relation to the health of the society as the whole. For example, the efficiency of modern vaccination in decreasing the risk of infectious diseases morbidity is well known. However, any patient may refuse to be vaccinated, declaring that the danger of disease for other people does not interest him, or say that to his point of view the risk of disease has already reached its minimal level, because a sufficient number of persons were vaccinated. In this situation it should be quite ethical to overcome the principle of the patients autonomy by carrying out programs of obligatory immunization.

Another weak point of the patients' autonomy model consists in the error of the initial thesis, that an individual is completely independent and self-sufficient in decision-making. In reality every person lives within a network of personal and social relationships (especially with his/her family members), which influence the nature of his/her final decisions.

And, finally, the principle of the patients' autonomy, unfortunately, does not offer any stimuli for the economy or just distribution of the health system limited resources. For this reason the principle of autonomy does not always work at the macro-level, when there is not enough facilities for the implementation of all that every autonomous patient wishes, especially when he wants "everything possible" to be done.

In the light of the mentioned limitations of ethics oriented at the principle of patient autonomy, an alternative *principle of social justice* got understanding and support in the system of health protection. It is based on the requirement of social justice in the distribution of limited health system resources, so that both advantages and economic loadings are justly distributed between different strata of the society. It is interesting that the problem of social justice played an important role in the origin and development of bioethics.

For instance, in the 1970-s there were many discussions in connection with the implementation of the newest (at those times) technologies of artificial dialysis in the clinical practice.

An ethical conflict in one of the hospitals in Seattle (the USA) got wide publicity at that period. A practical question had to be answered urgently: which patient was to be connected to the apparatus and, thus, his/her life would be prolonged, and who was fated to die because of having to wait for his/her turn. The principle of social justice is not always directed at immediate benefaction for the patient (as the principle of help and support requires) and does not always provide correspondence to the patient's auton-

omous choice of treatment (unlike the principle of autonomy). The principle of social justice stresses, that medical professionals have responsibility both before the society as the whole and before every individual patient.

The general principle of social justice provided the grounds for the development of related ethical principles, aimed at the regulation of the limited resources distribution. These principles presuppose such ethical criteria as equality, necessity, ability, efforts, social benefit and others. The standard of necessity is usually considered the basis of the health services resources distribution. This standard helps to estimate the patients' need in treatment on the basis of its probable outcome and the quality of the therapy results. A certain kind of therapy will be prescribed first to those patients, who have the best chances for its positive effect.

The principle of justice, as it is understood in bioethics, can be formulated roughly as follows: everybody must get what he/she is entitled to. The word "everybody" in this context concerns either a separate person or a group of people selected according to certain criteria. The principle of justice, like each of the other principles discussed above, has not an absolute, but only a relative force, it operates *prima facie*. If, for example, in a situation with donor organ transplantation it will be found that a patient, who's turn for operation has not yet come according to the waitlist, is in a critical condition, it would be moral to renounce the obligations effluent from the principle justice, and to follow the principle of non-harming. However, the failure to observe the turn in this case can be also interpreted in a different sense; here the same principle of justice can be used, if it is applied on the base of another criterion — the criterion of necessity, proceeding from the degree of its urgency. The principle of justice provides obligatory granting and equal availability of medical care. Each community sets the rules and order of granting medical care in accordance with its possibilities.

The discussion of the problem of justice requires decision-making concerning the macro- and micro-distribution. The problem of macro-distribution of goods and services is solved at the state level, it becomes the sphere of social policy and is directly related to the economic problems. They include the financing of the prophylactic and medical programs at different levels, as well as other forms of health work. However, for the medical workers the problem of micro-distribution of the health services limited resources is more urgent. In these situations which arise daily in every doctor's or trained nurse's work, medical indications should serve as the only criterion for the distribution of scarce medications and medical services. From the moral point of view it is impermissible to make the choice proceeding from a patient's social status, his connections or level of financial prosperity.

Although the principle of social justice is successfully applicable to the ethical discussions concerning the policy of health protection, its use in the clinical practice and in the relations between doctor and patient sometimes meets difficulties. The problem is that a doctor's education and experience is initially oriented at his patient. The doctors try to do everything possible for their patients, and the patients expect that their doctor will do his best in their interests. The critics of the principle of social justice assert that a doctor can not serve two masters — the patient and the society; and if a very expensive treatment is indicated, a doctor should do everything possible to provide it for his patient.

Another objection against the principle of social justice is the assertion that its ethical criteria, on the base of which the distribution of health protection resources is carried out, are hardly applicable in the real clinical practice. First of all, the "standard of necessity" in the distribution of resources presupposes that the rate of "necessities" is relatively permanent. However, the term "necessity" is rather indefinite, and a real patient's needs depend on specific circumstances.

Thus, the described principles of *help and support, non-harming, the patient's autonomy* and *social justice* are recognised as central in the modern biomedical ethics. Ethical problems are solved in the modern health protection with consideration of the content of the basic principles of bioethics, but the chosen methodological approaches or models can be different.

The description of relationships between the doctor and patient would be not full enough without the discussion of some conflicts of interests, which concern a doctor's professional activity. The medical tradition for a great period of time considered the assistance to a patient and maintenance of his/her health the most essential purpose of medicine. The modern formulation of this purpose is supplemented with a phrase: "within the framework of respect toward the patient's autonomy". More specific aims of medicine are traditionally acknowledged too; they include the maintenance of life, relief from pain and sufferings, restoration of physical and mental functions, taking care of the dying people and some others. Along with the existence of disagreements concerning the specific aims which should be included in the strategy of maintenance and support of a patient's health, there are other motivations and stimuli which compete with a doctor's focusing exceptionally on the problems of his patient's well-being. Such competitive motivations create a conflict of the doctor's interests, which shows up in the following variants.

1. The conflict between the doctor's interest in providing his patient's well-being and his interest in the maintenance his own health. Does a doctor have any obligations, which follow from his professional role, to render medical help in the cases which involve risk for his own health, for example, the risk of contacting an infectious disease?

2. The conflict between the doctor's interest in providing a patient's well-being and his own financial interests. The ethical question is, whether a legitimate competition is possible between professional and financial interests.

3. The conflict between the interest in a patient's well-being and the financial interests of the society. In addition to the traditional expectation, that a doctor must serve his patients and satisfy their medical needs, in the last decades a new expectation appeared, that a doctor should also serve the public need in the economy of medical charges, that is, he should operate as a "double agent". But can the fulfilment of this social need make a legitimate goal within the limits of the medical practice?

4. The conflict between the interest in a patient's well-being and the financial interests of the insurers — private companies or public programs. Can the insurers' financial prosperity legitimately compete in its importance with a patient's well-being? Is a doctor not only the patient's but also the insurers' "agent" ? If an insurance company is private, the doctor obviously can play a role of an agent of the stocks holders, whose primary purpose consists in increasing their income.

The relationship between a doctor and patient can have specific features related to their different cultural identification. A doctor and a patient can be citizens of different countries, speak different languages, and belong to different cultures (or subcultures within the limits of one country). For these reasons a doctor and his patient can have distinctions in their cultural understanding of acceptable ethical practice and very considerable divergences in their world view, in particular in the question, whether the universe is ruled only by natural laws, or the actions of spirit and magic are possible too.

A doctor and patient with different cultural views can have serious divergences in ethical issues. For example, they can disagree on the question, who has legitimate power in decision-making. The divergence can be caused by the problem of veracity in medical practice, the role of the family in decision-making concerning a patient's management or acceptable treatment of a child.

A doctor and patient who belong to different cultures can have disagreements on practical and metaphysical issues which influence the course of treatment. For example, a patient can believe that the discussion of possible complications of therapy and unfavourable outcomes of disease increases the risk of their development. The members of some cultures can defend the necessity of carrying out sacral actions, which cause considerable pain, with the purpose of driving evil spirits out of a child's organism. From the perspective of the western culture a doctor considers such beliefs irrational and potentially dangerous, however, from the ethical point of view the

respect of cultural features and traditions is an important component of a correct relationship between a doctor and his patient.

Racial, ethnic or national prejudices can also cause considerable problems in the relationship between a doctor and patient. Their overcoming is not only the issue of biomedical ethics, but also a task of the worldwide scale.

THE PRINCIPLES OF VERACITY AND INFORMED CONSENT

The relationships between the members of different medical professions (doctors, trained nurses, administrators, druggists and others) and the patients form a complicated social network, through which individual, group and state interests related to the health care issues are realized. There are norms which have a certain role in the ethical regulation of the relations between the medical staff and patients. The principles of truthfulness and informed consent are stated in The Declaration on the Promotion of Patients' Rights in Europe (Amsterdam, 1994) (Supplement 6).

The principle of veracity. This is a formal or deontological moral principle, which asserts that the actions or rules are morally correct, if they are directed at granting truthful information and have a goal of avoiding dishonesty in mutual relations. To be truthful means to give the interlocutor information, which is true from the point of view of the informer. Sometimes this rule is used in the form of prohibition of lies, i.e. the prohibition to give information which is false from the informer's point of view.

Traditionally the codes of medical ethics do not give enough attention to the veracity or deception and lies in the relationships between a doctor and patient. At the same time, the problem of a doctor's duty to give his patient true information is the most discussed question in bioethics. The question is formulated as follows: "can a doctor's paternalistic lies and the practice of patients deception be morally justified?" If yes, in which cases? One of the approaches to the analysis of ethical problems consists in asking more general questions. Is a lie always morally impermissible? Is it always correct to tell the truth? When answering these questions, we surely need to find good grounds for our position. If lies and intentional deception are always morally impermissible, then all the people including doctors should never resort to them. If lies and intentional deception are sometimes morally acceptable, it is necessary to try and define the situations which make such actions justified. After determining these conditions, it is possible to use specific examples of doctor and patient relations to estimate their acceptability.

On the whole, the problem consists in the moral conflict between striving to do the best for the patient from the perspective of good or harm concepts, and fulfilling some commons commitments, in this case — obligations to tell the truth.

The original approach of the Hippocratic school requires to act in a way which would benefit the patient. According to Hippocratic ethics, a doctor should say only those things, which can help a patient and avoid the information which can cause harm. The following words belong to Hippocrates: "Surround a patient with love and reasonable comfort, but mainly — leave him in ignorance concerning his perspectives, especially the possible risks which threaten him". A doctor's paternalistic lies, the so-called "holly deception", for a great while were considered quite acceptable in the relations between a doctor and patient. According to D. Oken's data (1961), 88 % of the questioned doctors in the United States reported that they usually do not tell the terminal oncologic patients the truth concerning their illness, following the traditions of Hippocrates.

The principle of veracity in the doctor and patient relations is assessed differently in different ethical systems. From the position of E. Kant's deontology, veracity is a duty of every person toward him/herself as a moral creature, and to lie means to humiliate one's own human dignity and to destroy one's self-esteem. Therefore E. Kant insisted that in all situations every person, including a doctor, has a direct obligation toward himself and others to be truthful. In W. Ross's deontology the obligation to abstain from lies and intentional deception is a *prima facie* obligation, which under certain circumstances can be inferior to other conditional (*prima facie*) obligations. A doctor's duty to provide his patient's medical well-being can be such an obligation in medicine. From the position of the "action — utilitarianism" theory, the question of the necessity to tell the truth is solved individually from the perspective of achieving maximal benefit in every concrete situation. The followers of the "rule — utilitarianism" theory in this ethical situation are confronted with a necessity to define the expedience of formulating exceptions from the rule, which forbids a doctor to give untruthful information to his patients. These exceptions should probably refer to the cases when there is convincing evidence that a patient does not want to know the truth about his/her disease, or that the information will cause him/her a serious psychological trauma. In these cases an adherent of the "rule — utilitarianism" theory should analyse, whether the harm done by revealing the truth to the patient would be compensated by the positive consequences, ensuing from the rule of prohibition of any lies in the doctor and patient relations. He will take into account also the fact that lies have remote consequences in the form breaking the doctor and patient relations.

In the 1970-s the attitude toward the principle of veracity began to change sharply in connection with the criticism of Hippocrates' paternalistic traditions and increased accent on the principle of respect toward a patient's autonomy. According to the data of questioning carried out by D. Novack (1979), 98% of doctors in the USA observed the rule of telling their patients truth about their disease and state in the everyday practice.

For the sake of rapprochement of the Hippocratic traditions and the respect toward the patients' autonomy we can make another effort at analysing the consequences of lies, remaining within the framework of Hippocrates' principle of non-malfeasance (non-harming). The point is that in the modern hi-tech medicine a whole team of medical workers participates in every patient's treatment, and it is difficult (and sometimes impossible) for all of them to support the same untruthful version of the patient's disease. In other words, in the conditions of modern medical practice there is a high probability that a lie will be exposed, and consequences will be extremely unfavourable for the patient.

Another direction of rapprochement between the positions of Hippocratic ethics and the principle of autonomy is the use of the "medical contra-indications" conception. In the same way as certain variants of investigation or treatment can be contra-indicated to a patient, sometimes, for example in depression or suicidal state, the revealing of truth can be considered medically contra-indicated.

The attempts of rapprochement of different points of view in regard to the principle of veracity can be rejected by radical supporters of the principle of veracity. From their point of view lies destroy trustful relations between a doctor and patient and make their coordinated actions impossible. In a number of cases it is simply impossible to abstain from giving a patient true information about his/her disease. For example, how can a doctor get a patient's consent for chemotherapy or radiotherapy without informing him that he has an oncologic disease?

In his relationships with the patients a medical worker acts as a representative not only of society as a whole but of his professional group too. Permanent lies violate the trust toward the profession. If a patient is convinced that doctors constantly hide unfavourable information from him, he will mistrust even quite truthful assertions, like "the prognosis of your disease is favourable", or "this surgical operation is not dangerous for you", or "chemotherapy will be effective in your case". It is possible that this circumstance can explain why many patients after the confirmation of an oncologic diagnosis turn to various healers and quacks even if their official treatment was effective. If patients mistrust the doctors, it is very difficult to reach success in the struggle against serious diseases, including tumours. Therefore both doctors, trained nurses, and medical administrators must be

truthful to maintain the attitude of trust to their professional group in the community.

The question about the patient's duty to know the truth is more difficult. The discussion of this issue should be held from the patient's position: why must "I" as a patient know the truth? "I" must know the truth precisely in order to preserve my "Self", i.e. to remain an autonomous personality, to be a responsible subject of my actions. Without the true information concerning the conditions of one's existence (including the information on the state of one's health), a person seams to shift the responsibility for his life events from himself to others (for example, a doctor), and by doing this, to renounce his subjectivity and freedom. Therefore the striving to know the truth is every person's duty, even when he is tied down by illness to a hospital bed. Surely, a sick person is naturally limited in his freedom. These limitations vary from most insignificant ones (in transitory colds), to most serious ones in the comatose states or changed states of consciousness in mental disorders. Therefore the duty to know the truth can not be imputed to every patient in an equal measure. Some people also have a psychological predisposition to live in an inferior, dependent upon others state. From the point of view of the autonomous personality morals, which dominates in the modern industrial world, this self-waver of one's own subjectivity is harmful. However, considering that this self-refusal is voluntary, this form of self-affirmation should also be respected. Among the representatives of different cultures patients tend to delegate the responsibility for the decision-making related to their disease to their close relatives or medical workers. To a certain degree this remark is correct in regard to traditional conduct of quite a number of patients. A doctor is obliged to take into account and respect these traditions.

It is legitimate also to discuss the question of a patient's duty to tell the truth. Must a physician aim at finding out the truth, and must a patient tell him the truth? A medical worker's duty to aim at obtaining maximally true information in all situations is determined by his professional task to treat the patients. Only complete and reliable information on the origin and course of the disease can guarantee correct diagnostics and effective treatment. The major condition of realizing this task is the development of trust in the patient toward the concrete doctor and the medical profession on the whole. A patient hardly will share the truth, if he/she is not sure that the physicians will observe confidentiality and the details of his/her personal life, disclosed to the medical personnel, will not be discussed with strangers.

A patient's duty to tell the truth is firstly grounded on his/her social nature and on the necessity to consolidate the spirit of trust in the "patient — medical staff" social unit. Veracity is everybody's moral duty, and illness does not diminish it at all. Besides, a patient often uses for his treatment

either state or institutional or family financial resources, which often are limited. The feelings of solidarity with a patient and the sympathetic attitude toward his needs are expressed in the redistribution of these limited resources to his benefit in the forms of state health care, institutional or family support. This circumstance creates another basis for the patient's moral duty to co-operate with the medical workers effectively, so that these limited resources would be used zealously. Naturally, this is impossible without his truthfulness.

A patient's obligation to tell the truth is grounded also on the principle of non-malfeasance. For example, when he comes to a doctor's consulting room, a patient has a moral duty to report about his infectious diseases, such as AIDS, tuberculosis, or hepatitis, which can be dangerous for the medical workers or other patients who come in contact with him. Another ground for a patient's duty to tell the truth is the fact that in the process of communication with the patients a doctor forms his experience concerning the importance of specific symptoms in correct diagnosing and increasing the efficiency of certain treatment measures. If a patient does not tell the doctor about wilful changes in using the prescribed medicines or distorts the information as to his complaints, he becomes accountable for forming the doctor's false knowledge about the diagnostic criteria of diseases or the efficiency or ineffectiveness of some medications. This false information can become a source of the doctor's erroneous actions, both in regard to the untruthful patient and to other patients.

The laws of Ukraine on health care provide a patient's right to know the truth about the diagnosis, prognosis and methods of treatment of his disease. A doctor's right to give the patients true information concerning the state of their health is limited by the requirement to deliver it in an understandable form and not to cause the patient harm by this information. A doctor's right to know the truth is not specially regulated by law. It is embedded in the traditions of doctoring and the administrative norms of modern medicine. The question usually concerns not a treating doctor's right to know the truth, which is usually considered obvious, but rather the right of other participants of the treatment process to have access to the information on a concrete patient's state of health. In the modern policlinics and hospitals medical help is frequently rendered not by one doctor but by a group of specialists, and each of them needs true information on the patient's state. Their right to the access to this information is provided by appropriate administrative norms. The question concerning the students' right to learn medical information on a specific patient's state of health is more difficult to answer, because they do not take a direct part in the treatment of this patient. Teaching at the patients' bedside is one of the most important elements in the medical workers' education. The traditions

and administrative order of clinics ground the students' right to participate in the patients examination, to implement diagnostic and medical procedures under experienced professionals' supervision, and consequently, to have access to the corresponding medical information. However, from the moral point of view, as the participation in the teaching process is not in the direct interests of a concrete patient, the students' right to have access to medical information and to the treatment and diagnostic manipulations must be conditioned by a voluntarily consent of the patient or his family members.

A patient's right to give the doctor truthful information about the state of his health and the circumstances of his disease development seems obvious on the face of it. However, the "truth" which a patient knows about his disease can concern not only him personally. For example, does a patient who is ill with a venereal disease have a right to report the truth about his/her sexual partner, who probably was the source of infection? The answer to this question varies depending on which of the two values outweighs in a specific society. If the preference is given to the public interest in the minimization of infectious diseases spreading, the patient not only has a right, but is even obliged (morally, and sometimes by law) to report about the partner. If the society values the inviolability of private life higher, the right to spread truthful information in this case is limited by the partner's permission to give this information to the doctor. In the democratic societies the inviolability of private life gets all the greater estimation and support (including its legal provision), so that the absolute priority of public interests is preserved only in connection with the group of extra-perilous infectious diseases. The lower is the social danger of a disease, the higher grow the values related to the inviolability of private life. The balance of values can not be predetermined by a certain rule. However, one should always remember that the right to tell the truth is not absolute and the inviolability of other people's private life is a major legal norm and a moral value of the modern civilized communities.

The principle of informed consent. Arguments about the veracity and lies in the medical ethics often arise in connection with the discussions of the requirement of informed consent. Today it is generally accepted that a competent adult patient has a moral and legal right not to be exposed to medical interference without his informed and voluntarily consent. It is quite clear that lies or even concealment of information seriously undermine the possibility of valid discussion and, consequently, the granting of informed consent. To give this consent and realize his/her right to self-determination, a patient must have the access to the necessary information, and doctors, as a rule, must provide it.

The requirement to get a patient's informed consent is a relatively new addition to the acknowledged ethical principles which regulate the doctor

— patient relations. The traditional codes of medical ethics do not acknowledge a doctor's duty to inform a patient about the risks and advantages of alternative diagnostics and treatment methods. The Hippocratic ethics includes the concept of therapeutic privilege, which consists in the concealment of information, which to the doctor's opinion is harmful for the patient and would worsen his psychological state. The therapeutic privilege is a component part of the ethical systems based on paternalism. The Hippocratic ethics does not exclude the informed consent, but only in the cases when, to the doctor's opinion, it will be beneficial for the patient.

In the liberal political philosophy the key thesis says that full information should be given, even if the doctor considers that it will not benefit the patient. In 1972 the doctrine and concept of informed consent were formulated and consolidated by law, and since that time they come into special notice of the specialists in bioethics. The pre-conditions for this doctrine were formed much earlier in connection with the investigation into the so-called "scientific" activity of the Nazi physicians in the concentration camps during the World War II. After the Nuremberg process in which the proofs of monstrous medical experiments carried out in the concentration camps were shown, the issue of the subject's consent became one of the main topics in bioethics. It should be noted that even before these events and in the world and domestic medical practice there was a long-term tradition of getting a patient's consent for surgical operations. However, the rule of informed consent has a wider approach than just receiving a patient's consent for operation, primarily because this rule requires the patients' and examinees' consent to be voluntary and given after they receive adequate information and make a free choice.

The principle of informed consent is designed to provide a respectful attitude toward the patients or examinees in biomedical research as to persons, and to minimize the threat to their health, socio-psychological well-being or moral values caused by the specialists' careless or irresponsible actions. Surgical operations, chemotherapy, protracted hospitalization and many other types of medical interference can have a serious impact on a person's ability to realise his/her life plans. The application of the rule of informed consent provides the patient's active participation in the choice of treatment methods, optimal not only from the medical point of view but also from the point of the person's values. In obedience to this principle, every medical interference (including a person's participation as an examinee in biomedical research) must include as an obligatory condition a special procedure of receiving the patient's or examinee's voluntarily consent, based on their adequate informing about the aims of the planned interference, its duration, expected positive consequences for the patient or examinee, possible unpleasant sensations, risk for life, physical and/or socio-

psychological well-being. It is also necessary to inform a patient about the existence of alternative treatment methods and their comparative efficiency. A substantial element of informing consists in telling the patients and examinees about their rights in this medical or research institution, and the methods of their rights protection in the cases of violation. Nowadays the rule of receiving informed consent from the patients and the people who participate in clinical tests or medical and biological experiments became a generally accepted norm. Chapter 2, article 28 of the Constitution of Ukraine states: "Nobody can be subjected to medical, scientific or other experiments without his/her voluntarily consent". In the "Bases of the Legislation of Ukraine Concerning Health Care" this position is specified in articles 42-45 (Supplement 7).

Medical interference fraught with the risk to the patient's health can be allowed as an exception in the case of urgent necessity, if the possible harm from the application of diagnostic, preventive or treatment methods is milder than the expected negative outcome, if no medical measures are taken, and if it is impossible to remove the danger to the patient's health by any other methods.

Risky methods of diagnostics, prophylaxis or treatment are allowed only with certain reserves: they must correspond to modern scientifically grounded requirements, be directed at the prevention of a real threat to a patient's life and health, be used with the patient's consent, if he/she is well-informed about their possible negative consequences, and the doctor is obliged to take all proper preventive measures to diminish the threat to life and health caused by them.

If the waiver of medical interference can result in grave consequences, a doctor is obliged to inform the patient about this. If the patient does not change his/her decision after this, the doctor has a right to demand a written confirmation, and if it is impossible to get it — to register the refusal by a proper document in the presence of witnesses. If the refusal is given by the patient's legal representative and it can lead to grave consequences for the patient, the doctor must inform the guardianship bodies.

Competence and voluntariness are the obligatory "threshold" elements or condition precedents of the principle of informed consent. A patient's or examinee's competence is the necessary condition precedent of the procedure of getting his/her informed consent. The law establishes a simple enough rule, which presupposes two states of a patient or an examinee — their competence or incompetence. Children and persons found incompetent in accordance with an established legal procedure, are considered incompetent. The right to give informed consent for an incompetent patient is passed to his/her legal representatives. The law expresses here only a generally recognised minimum of moral norms, setting aside a number of situations,

debatable and ambiguous from the ethical point of view. In particular, a child's rights to receive the information concerning his/her bodily and mental health and to have some control over things that are done to his/her body in the process of treatment, are practically not taken into account. Certainly, a child is not mature enough to make responsible decisions concerning the methods of his treatment without the adults' help. But this does not mean that the adult can fully replace him/her in the process of decision-making. Can we simply ignore an under-age patient's personality? Probably, a differentiated approach would be more justified. Depending on the level of individual development, the child should be given a greater or lesser volume of rights to participate in the decision-making concerning his/her treatment.

From the moral point of view the practice of forcing children to surgical operations by violence or deception is incorrect. The difficulty of receiving their consent, which indeed occurs in a number of cases, demonstrates only an insistent need of the doctors' education in clinical psychology and their active cooperation with professional psychologists in solving the problems of communication between very young patients and physicians. We should also take into account the possibility that legal representatives can make decisions which do not correspond with the patient's interests. In this case the doctors' duty is to defend the child's interests and take legal steps, which would limit the legal representatives' rights in this question. There were cases, when the parents refused to grant a permission for their child's life-saving surgical operation because of their ignorance or religious prejudices. In such situations the interests of incompetent patients should overweigh the rights of their legal representatives.

A patient's competence is understood as his/her capacity for autonomous decision-making. A patient, who's condition is very serious is not always competent. Competence is also decreased by the influence of considerable emotional stress and pain. It is principally important to determine whether a patient is competent. The determination of incompetence by a medical commission is based on the loss of the patient's ability to make decisions, which would promote his/her well-being, taking into account the values and preferences which he/she had expressed before. The bioethical practice works out the standards of competence, which have considerable specific differences in different fields of clinical practice.

The question concerning the volume of information, which a patient must get and understand, so that his consent could be considered informed, is extremely important. What are the criteria of the information sufficiency, and is it always better to get a greater volume of information? Research shows that a patient who had got protracted and detailed explanations of the essence and risk of a medical interference, can understand and repro-

duce only a very small volume of meaningful information. At the same time, the patients who had got less detailed information could understand and reproduce a greater volume of important facts.

Voluntariness in giving an informed consent is no less important than competence. The decision is considered voluntarily, if it is made in the absence external pressure on the part of doctors, authorities, relatives or friends. There are different forms of influence which can have a substantial impact on voluntariness. They include direct forcing to make a certain decision by threat or authoritarian imposing, as well as manipulation with information which, being outwardly objective, is selected in a way, which pushes a patient or examinee toward a decision, advantageous for physicians or researchers. A patient often supposes, that doctors can give up treatment, if he disagrees to participate in research or to use the method of diagnostics or treatment suggested by the doctor. Therefore when getting an informed consent, it is necessary to draw the patient's attention to the fact that his refusal will not diminish his rights and availability of alternative methods of medical interference.

Any illness, especially a grave one, has a serious impact on the patient's mental state and often limits his ability to make independent decisions. The helpless state makes the patient especially subjected to direct authoritarian dictate of the treating doctor. In these cases, even if there are no reasons to doubt the patient's competence, it is necessary to provide him/her a possibility to discuss the situation with his/her relatives or friends. A doctor should also remember about the patients' right for the consultation of independent specialists, provided by the existing laws. The firmest guarantees are given by the bioethical practice, when the requests for testing and research are independently examined by the ethics committee.

The procedural issues of informing the patient or examinee are important in the process of getting his/her informed consent. To determine the optimal volume and content of information the specialist can follow special norms, the so called *standards of informing*. Several standards were proposed, and among them "the professional standard", "the rational person standard" and "the subjective standard" are of the greatest practical interest. According to the first standard, the volume and content of information is determined by the traditionally formed practice of a specific medical community or medical institution. In the process of training a future doctor learns from his teachers not only the doctoring techniques, but also elementary skills of communicating with patients. This is a spontaneously formed standard of medical practice, which is usually involuntarily mastered by professionals. In a stable society with a well formed health system and generally acknowledged moral norms of doctoring this standard is effective enough. However, in a society which is in the process of stormy social and

political transformations where new codes of ethics are only being developed, the appeal to traditional norms can have only preliminary value. In this situation "the rational person standard" is more appropriate. This standard proposes to imagine a kind of "average citizen" and answer the question which information and in what volume may he/she need in order to make a grounded decision concerning his/her consent or disagreement to a certain medical interference or to his/her participation in biomedical research. A doctor or scientist should be able to model in his/her imagination a patient's or examinee's rational conduct and, according to the result of this mental experiment, to build the tactics of informing.

"The subjective standard" suggests to help the patient in making a rational decision by supplementing the information, useful for an "average patient", with facts corresponding to this concrete individual's specific interests. If, for example, this patient's case history includes the data on a heart disease he/she had before, the information about the risk of complications should focus on the possibility of cardio-vascular disturbances, although they and not characteristic for an "average patient". "The subjective standard" proposes the tactics of individualizing the presented information. Considering that some patients' educational level is low, in a number of cases there is a serious doubt that they are able to understand the presented information correctly. T. Beachamp and J. Childress offer the following way out of this situation: "Successful informing of ignorant in medicine patients about new and specific subjects can be attained if analogies from their everyday life are used as explanations. For example, to explain the risk, expressed in a numerical form, a professional can use a comparison to the probability known to the patient from preceding experience of risk involved in some actions, such as the risk involved in driving a car or in the work with electric devices".

From the practical point of view it is better not to use a lot of special terms, which can be either not understood at all or misunderstood. It is also important to take into account the psychological influence of the used words. The information that the probability of survival is 50% gives more hope than the report that the probability of death is 50%, although from the mathematical point of view the risk is identical. When the patients learn the information that a certain medical interference involves even a low degree of fatal risk, as a rule this sharply reduces its preference, although its remote consequences can be much more favourable. To understand the information is not the same as to accept it. A patient who has cancer and knows his/her diagnosis well can still be convicted that really he/she is healthy or that the tumour is benign. Therefore, proceeding from this false conviction, he/she can give up chemotherapy or refuse the suggested surgi-

cal treatment. As the sociological research shows, quite a lot of patients are not eager to know the details concerning the methods of treatment and the risk they involve; they prefer the treating doctor to make the choice for them. The number of people not interested in learning this information reaches 50% of all the patients. A doctor must respect his patient's opinion and should not force the undesired information on him/her. On the other hand, an examinee's participation a clinical test or biomedical experiment is impermissible without his/her knowing and understanding the content of research and the risk it involves.

Having received the objective information about the medical interference or scientific research, the patient or examinee must decide whether to give his/her consent or not. The decision-making is an independent process which is only prepared by objective informing. It requires time. Thus, a patient or examinee should not be compelled to sign the consent form immediately after receiving the information. It is necessary to give them some time to think, ask for their relations' or friends' advice or consult a specialist. It is also necessary to remember that the consent initially given by an examinee or patient can be revised by them later. Therefore the law provides an examinee's right to stop his/her participation in research at any stage, and a patient's right to decline the treatment. The authorizing, as well as informing, can be made both in verbal and in written form. In its essence it means initiation, i.e. conclusion of an agreement between the patient and medical specialists, which will bind them with certain contract relations. These relations determine mutual legal and moral obligations of parts and establish the forms and extent of their responsibility.

The verbal form of informing a patient or an examinee creates favourable grounds for manipulation with their decision. Holding back some facts, incorrect information about the comparative risk of alternative treatment methods, the concealment of information about preceding negative experience of using certain medical procedures, overstatement of the chances for success of the offered investigation or medical interference — all this can violate the principle of voluntariness. It is also necessary to take into account that a physician can resort to such violations being unaware of what he/she is doing. A scientist carried away with the development of a new method of treatment is naturally inclined to exaggerate the merits of his/her innovation in comparison to the existent methods. In this sense written filling in of a special form of informed consent creates more possibilities for control over the objectivity of given information.

The procedure of receiving the informed consent is called to realize the moral idea concerning the recognition of a patient or examinee as a person,

who has a right to participate together with the medical workers in decision-making on the issues of his/her treatment. The rule of informed consent finds its expression in the form of certain ethical norms, codes and declarations, adopted by the international and national medical associations. A doctor and a research worker are obliged:

1. To provide respectful attitude toward a patient or examinee in biomedical research as an autonomous person which has a right to make free choice and control all the procedures or manipulations with his/her body in the process of treatment or scientific research.

2. To minimize the possibility of moral or financial damage which can be causal to the patient by careless treatment or experimentation.

3. To create conditions which promote the responsibility in the medical workers and researchers for the patients' and examinees' moral and physical well-being.

The procedural aspects are regulated by the national laws, orders and instructions of the health care bodies and the internal rules of the medical and research organizations. The tradition of verbal informing has a certain advantage: it seams less formal and more confidential. On the other hand, verbal informing practically excludes independent control of what is really told to a patient or examinee and reduces the doctors' and research workers' responsibility for the quality of informing. Thus, it creates the conditions for the violation examinees' rights.

Informed consent is very important for the patient's socio-psychological adaptation to new living conditions, which can possibly follow a medical interference. The discussion of the treatment, its aims and possible consequences with the doctor increases a patient's psychological readiness to necessary changes in his/her life mode. As a result, it promotes effective adjustment. The rule of informed consent not only regulates certain procedural norms, which precede a serious medical interference or participation in an experiment, but also aims at enriching personal cooperation of doctors and patients (examinees) during the treatment or scientific research process.

The principle of informed consent should not be considered only as a measure undertaken in connection with the risk of doctors and researchers causing damage to the patients or examinees. It is more justified to consider that the prevention of this danger is a very important, but not the only or the main task. The principle of informed consent should be understood as a norm of cooperation of a doctor and a patient with the purpose of their joint grounding and coordinating the optimal method of medical interference. The principle of informed consent should be considered not as an end in itself but as a means of providing a partner dialog of the interested parties, which are the doctor and patient.

MODELS OF RELATIONS BETWEEN A DOCTOR AND A PATIENT

The problem of doctor and patient relationship is considered the prevailing issue in the medical ethics, which develops together with the medical science and practice. The contacts of doctors and patients occur every day, and every time they are unique. In some substantial features these cooperations are well-organized and traditional: as a rule, both parties behave in these cases in a conventional way, "as they should", often without even realizing this. In a stable social system the course of such events is usually formed in accordance with certain norms, the observance of which is not specially controlled, but which people follow strictly enough. It is therefore possible to talk about the social role of a doctor and the social role of a patient. These norms and roles organize the behaviour of the parties: each of them from the beginning of the contact understands well enough what it can expect from the other party and what are the other party's expectations. A doctor's social role, and hereupon the social role of a patient can be differently understood in different cultures and societies. Thus, we have reasons to talk about different models of doctoring.

To describe different types of relationships between a doctor and a patient we can use a number of metaphors: a parent and a child, partners, participants of an agreement, a technician and a client, and friends. In accordance with these metaphors, we can ground the existence of five basic models of relationships in the field of health care: the paternalistic, collegial, contract, befriending, and technical models (J. F. Childress, M. Siegler, 2001).

The paternalistic (pastor, paternal) model is based on centuries-old tradition of medical practice. In this model a medical professional, in particular a doctor, is the decision-making centre and possesses the "moral" power in the asymmetric and hierarchical relations with a patient. We can draw an analogy with the relations of a pastor and parishioners, parents and children. In the paternalistic (from the Latin *pater* — father) approach a doctor plays the role of a father, who not only takes care of his unwise child's well-being, but also determines what is good for the child. The term *paternalism* originates from the language of socio-political theories and characterizes such a type of relations between a state and its citizens or subjects, in which the state initially considers itself the absolute representative of their well-being and their interests, i.e. makes decisions and operates on their behalf, taking absolutely no trouble to find out and consider their opinions. The citizens, on their part, proceed from the belief that the state has a full authority to decide what is good for them, but at the same time it is obliged to take care of them and be their guardian. As a result, the alien-

ation of the citizens' rights and freedoms occurs, and in this case they actually appear to be not so much citizens, in the real meaning of this word but rather the subjects, subordinates of the state. As a phenomenon of the social and political culture, paternalism concerns not only the relations of the state and citizens but also all the spheres of the society life, where any kinds of authoritative relations show up, i.e. relations of some people's domination and submission of others. One of such spheres is the field of health care.

Medical paternalism assumes that a doctor can trust only his own judgements as to a patient's needs in treatment, informing, and consulting. The paternalistic position allows to justify the patients' compulsion and deception, or the concealment of information from them if it is done in the name their well-being. Paternalistic relations are filled with subjective content and built as a kind of interpersonal communication. It is motivated by the intention to help a suffering person and avoid causing him harm. We can say that its moral characteristics presuppose love toward one's neighbour, charity, mercy and justice. However, the parties of this relationship are in unequal position. The doctor acts a part of a "father" who possesses certain scientific knowledge and is able to apply it. The patient acts a part of an ignorant child, who's moral virtue consists in the disciplined implementation of the orders and prescription of the "senior". Paternalism in the communication with patients remains a norm for quite a number of modern physicians, and many patients perceive the paternalistic attitude toward them as quite adequate. Paternalistic positions prevailed and were not called in question up to the middle of the past century. The subsequent sharp turning away from them was conditioned by the action of a number of reasons, including the rapid increase of the educational level of the population and the recognition of the fact that in a pluralistic society different systems of moral values coexist. A doctor's values, and consequently, his picture of a patient's well-being, can substantially differ from the patient's own values and his picture of his well-being. There are quite many people for whom a doctor's paternalistic attitude is psychologically most acceptable. Their personal preferences should be respected, despite the imperfection of this model from the moral point of view. Paternalism violates the rights of a patient as an autonomous person, who makes vitally important decisions and controls his/her state independently and freely. As a matter of fact, it involves an element of humiliating the patient's personal dignity, because the co-operation is built not "horizontally" (equally in rights), but "vertically", as the relations of power and submission. A patient, figuratively speaking, is forced to "look up" at a doctor. Paternalism is a natural and most adequate form of a doctor's attitude towards sick children and other patients with limited capability. The circumstance that at the moment of making a responsible deci-

sion the child's or mentally incapable patient's interests can be protected by the participation of their legal representatives (for example, parents), does not belittle the appropriateness and moral justification of the paternalistic attitude toward them in the context of everyday doctoring relations.

The collegial (partners) model of relations between a doctor and a patient provides much more possibilities for the realization of an autonomous person's values. This model stresses that the medical professionals and their patients can be partners or colleagues on the basis of recognising the value of health. The recognition of common values of the involved parties unites this model with paternalism. The principle difference consists in the accent the collegial model makes on the equality of both parties' rights in the interpretation of these values, including health, along with the respect to the personal autonomy of all the participants of the relationship. The prototype of this model are "adult-adult" relations. Within the framework of this model a doctor helps a patient to help himself, while the patient uses the expert's help to realize their common goals (his own and the doctor's). It is assumed that the participants have approximately identical rights, are interdependent (i.e. one needs the other) and are engaged in the actions which satisfy both parties to a certain extent. Moreover, this model proceeds from the idea that the doctor does not know the best solution, and the essence of therapeutic co-operation consists in the search for it. In the framework of this model a patient appears to have equal rights in the co-operation with the doctor. In order to act his/her part, the patient must receive from the doctor a sufficient volume of truthful information concerning the state of his/her health, variants of treatment, prognosis of the development of disease, possible complications, etc. Being to some extent equalised with the doctor in regard to possessing information, a patient becomes able to take part in making concrete decisions concerning his/her treatment, operating almost as an equal in rights ally of the treating doctor. In this case he/she realizes the inalienable personal right to the freedom of choice.

This model is rarely applied in practice and its value has a normative nature. It demonstrates the desirable and even obligatory moral direction of medical practice and science. As a normative model it stresses the equality of the partners' values and the respect towards the autonomy of both medical professionals and other persons — patients or volunteer participants in medical research.

The complexity in the practical application of this model depends on the difficulties of achieving harmony of interests. The medical staff and the patient can adhere to different value orientations. They can belong to different social classes and ethnic groups. In the conditions of commercial medicine a doctor has objective (conditioned not by his personal traits but

by the real situation) personal interest in minimising his own expenses and maximising his profits, while the patient's interests are opposite, they consist in getting the maximal available help for minimal costs. At the same time we should take into account that there are some regions in which the relations between a doctor and a patient can really have collegial nature. This concerns the cases of protracted chronic diseases. The volume of knowledge which patients acquire during many decades of their chronic illness in certain aspects can be considerably bigger than a young and inexperienced doctor's. In these situations the communication of a patient and a medical worker can approach the ideal of collegial model, reminding a professional concilium, in which the knowledge of one party supplements the knowledge of the other. Psychotherapy is another field of this model clinical application; in psychotherapy both partners' cooperation is a necessary condition for attaining success.

The contract model. In this model the relationship between a doctor and patient is based not only on the legal content of the "contract" (agreement) concept but also on its general, symbolic understanding. The ideal of contract as the most adequate form of social relations between people was formed in the epoch of Enlightenment. Instead of the heritable and seemingly entitled by God monarchical power, enlighteners advanced the idea of public agreement. They considered that authority should not monopolistically belong to a group of people by virtue of their "breed" or class privileges. The people have a right to delegate plenary powers to a ruler by expressing their free will, but he concludes with them a kind of a contract, which determines the general aims of his authority and the scopes of its plenary powers. The violation of the terms of contract by the ruler gives the people grounds for dissolution of this contract and depriving the ruler of his power by force. In the modern society not only political relations but also labour, family and many other social connections are built to a great extent on the contractual role distribution and mutual responsibility.

The contract model of relationships between a doctor and patient presupposes that medical professionals conclude a series of specific contracts with their patients. The prototype of the contract model were specific contracts, in accordance to which individuals consented to exchange goods and services, and the implementation of which was supported by state sanctions. According to R. Veatch's opinion, the contract model is the best compromise between the ideals of partnership with the accents on equality and autonomy, and the realities of medical practice, when mutual trust can not be guaranteed. In this situation the contract model is a unique possibility to share responsibility, protect the parties' equality and autonomy and provide the honesty of the participants of the medical service process. The contract form of relations allows to avoid the failings which threaten a

patient's freedom, and which are inherent to the paternalistic and technical models. At the same time it does not refer to the illusive possibility of a patient's participation as the doctor's "colleague". A patient voluntarily establishes relationships with a doctor on the terms which he considers advantageous and possible. By this contract he/she can delegate certain powers to the doctor, so that the specialist can adequately do his professional duties. The contract model more realistic than the collegial one. It takes into account the impossibility of a doctor's and patient's equality, i.e. the inevitability of the "vertical" relations of dependence. This dependence, however, is established on fully determined terms. If the conditions are not observed, a patient has a right to consider the contract invalid, to deprive the doctor of those powers which he got by virtue of agreement, and to demand for compensation.

The befriending model. The relations between a doctor and patient can be based on friendship. This model is grounded on the proposition that a good doctor always becomes a friend for a concrete patient and all the patients in general. In these friendly relations the patient trusts the doctor, and the doctor' friendship shows up, besides other things, in his efforts to give effective help and in his goodwill. Sure, the analogy with friendship has a relative nature, and the friendly relations between a doctor and patient are limited by their special orientation at achieving the goal of the patient's healing. In addition, different factors, including financial obligations, influence these relations. Nevertheless, the befriending model of relations reflects the moral orientation at achieving equality, autonomy and observing the rights of both parties. As E. Kant determined the friendship as a union of two individuals through equality, mutual love and respect, the befriending model contains the components of both paternalism (love or care) and anti-paternalism (equality and respect). This model reminds partnership. Indeed, medical friendship is very close to medical partnership, but for the fact that the first stresses the intensity, strength and depth of relations, and the second makes an accent on restraint and limitedness of relations.

The technical (engineering) model. The relations of doctor and patient in this case are compared to the relations between a technician (or engineer) and his client. A patient's body is compared to a mechanism, and the illness is interpreted as its breakage, which a doctor, as an engineer or technician, should remove. In this model a doctor offers or carries out technical service for the patient as a user. The essence of doctoring comes to the manipulation with the patient's body. The doctor, using certain physical influences aims at returning the patient's physiological mechanism to the position of equilibrium. The engineering model is based on the understanding of medical activity as a field of applying objective scientific knowledge about the natural mechanisms of the human organism vital functions. The objective knowledge

determines the choice of the treatment method, which is applied as a technical procedure. The patient's well-being is also understood as an aggregate of objective signs: biochemical indices, values of blood pressure, gases metabolism, the X-ray data, etc. Considering that a patient does not possess necessary scientific knowledge about the state of his/her health, the account of his/her opinion in the choice of medical measures is not only useless but can even be harmful because of subjective estimations. The patient's personal opinion on what is good for his/her health does not deserve any attention from a professional physician's point of view because it is biased and non-scientific.

The engineering model is based on an out-of-date picture of the nature of scientific knowledge. As the modern philosophy of science shows convincingly, the objective knowledge is "loaded" with a considerable amount of pre-conditions unrealized by the scientists. These preconditions include personal and group interests, as well as certain moral preferences, which act quite an important part. The modern moral standards of medical activity most decisively demand the avoidance of de-personalisation of relations between a doctor and patient, they require respect towards a patient as personality. However, is the de-personalisation always a result of a physician's morally inadequate attitude toward the patient? The point is that in a number of concrete situations, common for the modern medicine, a patient objectively can not appear as a personality to a full degree. As a result of a high degree of labour division at a modern clinic equipped with hi-tech appliances, as a rule, a patient has personal contact only with his/her treating doctor and a nurse. Quite a number of specialists are occupied with the implementation of special procedures, which practically eliminate the elements of personal contact with patients. The de-personalisation of relations with patients in this case is not a result of amoral attitude, but is a consequence of the modern medical practice technisation.

The technical model of relations between a doctor and patient can not be considered desirable or possible. It is hard to imagine that a medical, professional would operate like a technician only with "factual" material which does not have any value or ethical characteristics. The point is that the basic medical concepts, such as health and illness, are considered from the position of their intrinsic values. However, if a "technician" works at an organization or has direct relations with patients, he also serves certain values. The technical model offers autonomy to the patient, whose values become dominant due to the morality and purity of medical professionals. In other models, such as contract, partner and befriending, moral responsibility is distributed among all participants, because they, in a certain sense, have equal rights.

Section IV
RELATIONS BETWEEN A PATIENT, HIS/HER FAMILY AND THE MEDICAL PERSONNEL AT THE MEDICAL INSTITUTIONS

"Doctoring… is an ability to place yourself, the patient, science and culture in time and space."

A. F. Bilibin

THE MEDICAL AND ETHICAL ROLE AND RESPONSIBILITY OF THE MEDICAL PERSONNEL AT THE MEDICAL INSTITUTIONS

The modern medical care has a complex and successive nature. It is rendered at different outpatient and inpatient medical institutions, including policlinics, consultations, dispensaries, hospitals, invalid and old people's homes, and hospices. The personnel of these institutions includes not only doctors but also qualified nurses, medical assistants, interns, technical workers, other medical and paramedical professionals, administrative, social and auxiliary workers. The modern bioethics also carefully analyses the role of a patient's family members in decision-making. In this situation the discussion concerning a patient's rights and the corresponding duties of the medical workers should be extended beyond the limits of the ethical analysis of isolated doctor-patient relations, discussed in the previous section. It will be useful to examine a patient's rights additionally from the perspective of the medical institutions personnel ethical responsibility and the role of the patient's family in making medical decisions. The major of these rights is the right to the protection of confidentiality, which becomes more topical in connection with the team approach to a patient's management and the growing number of persons who have access to medical information.

A patient's rights must be respected and protected by all the participants of the diagnostic and treatment process and the patients' management. 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" (Council of Europe, 1997; Supplement 5) reflects this necessity. In different countries additional documents on the patients' rights are adopted, for example, "The Code of Patients' Rights" of the American Association of Hospitals. Such materials sum up the patients' rights, but their certain failing consists in their vagueness as to whether they are analogues of professional ethics codes, or provide sets of moral rights, or list legal rights, which follow from a concrete legislative base. In spite of the mentioned vagueness, these lists of patients' rights have substantial value, because they remind both the patients and all the people who take part in their management that a patient must be treated as a personality. A patient is not simply an object for professional manipulation or an inferior individual who has lost all his/her rights, including the right to self-determination, only because he/she became a patient.

The patients' rights began to be formulated and discussed relatively recently. They include a patient's right to confidentiality and adequate information about the state of his/her health. The patients' rights are usually connected with the corresponding (reciprocal) duties of the medical specialists. For example, the proposition that a patient has a right to confidentiality is complemented by the professional ethical codes provision that the medical workers are obliged to respect the patients' confidentiality.

Effective health care depends on the co-operation between a patient, doctor and other medical workers. The optimization of a patient's treatment is achieved on the basis of open and honest co-operation, individual approach, respect to the personal and professional values. An atmosphere of mutual understanding, respect of the patients' rights, and responsibility of the patients, their families, doctors and other persons involved in the provision of diagnostic and treatment measures should be created at the medical institutions. This ethical atmosphere would provide conditions for the patients' participation in the decision-making concerning the choice of therapy and other aspects of their management. The personnel of the medical institutions should understand the cultural, racial, linguistic, age-dependent, sexual and other distinctions of the patients, as well as the disabled people's needs.

Unfortunately, patients are often dissatisfied by the situation in which the treatment is provided. Sometimes they consider that the organization of the diagnostic and treatment process is oriented at the creation of comfort for the personnel, rather than at arranging comfortable conditions for the patients. Patients often suppose that they are considered as "clinical cases"

and not as persons. An objective complication in the establishment of correct relations between medical workers and patients is caused by the circumstance that professionals in certain situations feel obligations not only toward their patients, but also in relation to other persons and groups of persons, and to the society in general, i.e. they find themselves in the situation of interests conflict.

In the relations between a patient and the medical personnel a special role belongs to trained nurses. A nurse is challenged with the same moral problems as the doctors but in addition with the problems arising from her professional role. Just as a doctor, a trained nurse sometimes has to make a choice whether to do what she thinks will promote a patient's well-being, or to act on the basis of respect toward the patient's self-determination. Different models of co-operation are possible between a trained nurse and patient, including the paternalistic and different variants of contract models, which allow the patient to realize his/her right to self-determination and respect the nurse's right to refrain from doing anything that does not correspond to her autonomous moral rights.

Another dilemma which a trained nurse often encounters is related to her position in the system of medical help. On one hand she participates in taking care of the patients, and on the other — guides and supervises the work of the medical attendants. Usually a trained nurse is responsible both for care giving and for the carrying out certain diagnostic and therapeutic measures. At the same time she has a limited influence on the process of decision-making concerning the patients. In addition, a nurse is usually supposed to help a doctor who makes the diagnosis, prescribes medication and expects that the nurse will carry out his instructions well and in full. In some cases trained nurses find themselves in a situation when their duties in relation to a patient conflict with their duties in relation to the doctor. The following ethical questions may emerge. Should a trained nurse obey a doctor's orders if she has good grounds to consider them erroneous and possibly harmful for the patient, and the doctor refuses to acknowledge his mistake? What should a nurse do if she is sure that a doctor violates a patient's right to self-determination, for example by concealing important information or reporting false information deliberately? The Code for Nurses of the American Nurses Association defines professional corporate obligations and obligations in relation to society and the patients. This document does not contain the obligation to execute doctors' orders, traditional for other codes of nurses. The importance of professional autonomy and protection of the patients' interests is reflected in the following thesis: "The nurse acts to safeguard the client and the public when health care and safety are affected by the incompetent, unethical or illegal practice of any person."

An additional circle of moral problems in the nurses professional activity is considered by the feminist ethics. It analyses the principles of practically monopolistic representation of women in this profession, which is related to care giving, i.e. a historical sphere of activity of servants, slaves, colonial population, and minorities. The field of the feminists' attention includes the factually inferior position of a nurse and the ethical problems related to this position, including the problems of women discrimination. The feminist ethics actively supports the ideals of a nurse's professional autonomy owing to which she should be ready, at certain circumstances, to resist a doctor's authority in defence of a patient's interests. Some distinctions in the ethical views of men and women can sometimes be pre-conditions for ethical conflicts between doctors and nurses, and these conflicts are supported by distinctions in the extent of their professional authority.

At the same time, the traditional ideals of trained nurses work have a steady enough position, and many professional codes reflect a nurse's obligation to "follow a doctor's orders". The followers of the traditional views suppose that clear division of professional responsibility and professional roles provides the best pre-conditions of adequate functioning of the diagnostic and treatment institutions. The respect toward a doctor's authority is grounded on the fact that doctors have a higher level of professional readiness to act in the majority of clinical situations. On the other hand, the patients' emotional needs are better satisfied by the nurses, which in their traditional role can operate as "substitutes mothers" in relation to patients. From this point of view the nurses inferior position provides the most effective management of patients, when a doctor acts as a decision-making centre and the fulfilment of his orders helps the patients to receive timely and high-quality medical care.

Practically all professional nurses beginning with Florence Nightingale, as a result of long-term working experience, came to a conclusion that a certain morally-ethical base is as necessary for skilled care-giving as special technical knowledge, and it is impossible to treat a human being as a broken mechanism. Trained nurses are not simply doctors' assistants and performers of their commissions but rather representatives of an independent profession, which have skills of complex, comprehensive care-giving and rehabilitation, and possess knowledge in the field of psychology and psychotherapy within the limits of their competence. The well known nurse Florence Nightingale said almost 100 years ago: "A nurse must have a triple qualification: cordial — to understand patients, scientific — to understand illnesses, and technical — to take care of patients". The Code of Ethics for Nurses was developed and adopted by the International Council of Nurses (ICN) in 1953. It says that the medical ethics should be based on the observance of human rights, including the relationships of nurses with patients and with each other in a certain social and professional environment. In

1994 a textbook on the ethics for nurses was issued under an aegis of ICN; it described specific situations in which nurses could find themselves and gave detailed comments concerning the proper behaviour in such cases. In 1983 the graduates of the nurses school in Michigan (the USA) first vowed "The Florence Nightingale Pledge"* named after the founder of scientific nursing. This Pledge, the text of which has much in common with the Hippocratic Oath, sounds as follows: "I solemnly pledge myself before God and in the presence of this assembly, to pass my life in purity and to practice my profession faithfully. I will abstain from whatever is deleterious and mischievous, and will not take or knowingly administer any harmful drug. I will do all in my power to maintain and elevate the standard of my profession, and will hold in confidence all personal matters committed to my keeping and all family affairs coming to my knowledge in the practice of my calling. With loyalty will I endeavor to aid the physician in his work, and devote myself to the welfare of those committed to my care."

A nurse is constantly with the patients, and the quality of care taken of them and their convalescence depend on her to a great extent. A nurse's field of activity is wide and many-sided. It includes healthy people with their problems, the environment, the prevention of diseases, the providing of the patients' proper nursing, and finally, human socially-psychological problems. A nurse's personality, the methods of her work, her style, her ability to communicate with patients, her technical skills of psychological work — all this in itself can serve as medicine and render the curing action. In addition a nurse has to execute the management and educating activity.

In the conditions of a medical institution the first contact of a patient with the medical personnel and, in particular, with the nurses, is especially important, because it determines the future relations of both parties: the feelings of trust or mistrust, friendliness or hostility, the presence or absence of partners relations. Everything in a nurse, beginning with her appearance, should dispose a patient to her (her smartness, accuracy, her hair-do and facial expression). Partners relations are formed between a nurse and a patient if the patient feels that the personnel sincerely wants to help him/her. Only in this case a confiding dialog is possible, in which the nurse learns the necessary information about the patient, the traits of his/her personality, his/her opinion about the disease, hopes for getting well, plans for the future.

A nurse should remember that the partners relations with the patients must not become too familiar: the leading role should always remain with

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* In 1893, Mrs. Lystra E. Gretter and the Farrand Training School for Nurses wrote an adaptation of the physician's Hippocratic Oath for nurses. It was named the Florence Nightingale Pledge in honor of the esteemed founder of nursing. http://nursing.about.com/od/historyofnursing/a/pledge.htm *(the translator's note)*.

her. A patient must always be sure that their conversations are confidential. Knowing the patient's personality traits and his experiences, a nurse should tactfully explain the patient not only his rights, but also his duties, tell him in an understandable form about the necessary investigations, about the preparation to them and the forthcoming treatment. A patient's refusal to be subjected to a certain investigation or treatment must not cause negative attitude toward him on the part of the medical personnel.

A nurse's duty consists in being honest and truthful with a patient, but her talks about the diagnosis and the features of the disease must not go beyond the limits marked by the treating doctor. The same concerns the nurse's conversations with the patient's relatives. A doctor and a nurse can have different views as to the specific features of managing the patients. These issues should be discussed between them to achieve consent and facilitate their further joint work. A nurse's right to defend her point of view must be combined with high demands to herself, an ability to acknowledge and correct her mistakes, discovered by her or by her colleagues.

The humanism of her profession provides a basis for the protection of a nurse's personal dignity, her physical inviolability, and her right to receive help in the execution of her professional duties. Certainly, the standard of her life should correspond to the status of her profession. Medical workers, including trained nurses must not be forced to work on unacceptable for them terms.

The diagnostic and treatment institutions and the commands of medical professionals, which work in them, execute different functions. They are engaged in the prevention and treatment of diseases, propaganda of the healthy life style, consecutive management and rehabilitation of patients, graduate and postgraduate education and research work. All these types of activity must be carried out only on the condition of full appreciation of a patient's value and dignity, absolute respect to his personality and his rights. These rights are violated with irreparable harm for the mutual relations between patient, his family and the medical personnel of the diagnostic and treatment institution in the cases of *medical errors* and *iatrogenic disorders*. Accidental errors made by a doctor as a result of some circumstances which don't involve any elements of indifference, negligence, professional ignorance or evil motives are considered medical errors. In other words, medical errors are mistakes made by a doctor in the course of his professional activities, which are a result of his honest delusion and do not involve any signs of crime or misconduct.

Unfortunately, in the clinical practice accidents are possible which involve unfavourable outcome of treatment, operation or other medical interference, when a doctor was unable to foresee the trouble, in spite of his conscientious attitude to his official duties. Such casual outcomes of medic-

al interference include mortal cases caused by narcosis, when the procedure of anaesthesia answered all the rules and requirements of medical science, and the death was the result of a specific state of the patient's organism, which in some cases are very difficult to diagnose. The same category includes cases of sudden death after the use of different medicines, when the mortal end is caused by the sensitiveness of the organism, and not by a mistake in the course of a medical procedure which was blameless from the point of modern medicine. In these cases the mortal outcome is conditioned by casualties which do not depend on the doctor's actions. For these reasons medical errors and accidents do not involve criminal proceedings. However, in order to avoid the repetition of similar errors and to prevent them in the future medical practice, such cases are systematically investigated in detail at clinical anatomic conferences or by the treatment-control commissions.

Professional errors occur in a doctor's, as well as in any other specialist's practice, but medical errors have a much greater social resonance. A doctor has moral responsibility toward his patients and society (the strikes of doctors are forbidden by law in all the countries).

The most common type of medical errors are made in the diagnosing and the choice of the proper treatment methods. The main reasons of medical failures consist in the briefness of a patient's observation, untypical symptoms, and the avalanche-like stream of the newest medical information. The medical errors include mistakes made in the medical documents, which have legal force.

The medical workers' actions, carried out both correctly or improperly can cause changes in the patients' state of health, i.e. they can result in the development of para-therapeutic or iatrogenic disorders. The iatrogenic disorders (in Greek *iatros* means doctor and *gennao* — to make or cause) were originally considered as psychogenic disorders, which develop because of the medical workers' deontological errors — improper, careless utterances or actions. Later the group of iatrogenic disorders was expanded, now it includes disorders related to the negative consequences of medicinal therapy and physical damage from medical interference. Thus, the term *iatrogenic disorders* is understood in two senses: the first — iatrogenic disorders caused by impact, in accordance with the WHO concept of causing harm to a patient by prophylactic, diagnostic or treatment manipulations; the second — iatrogenic disorders caused by communication, which are examined by the medical deontology and biomedical ethics.

In accordance with the requirements of the International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10), every pathological process which develops as a result of any medical procedure (carried out both correctly or improperly) — medicinal therapy,

diagnostic or medical manipulation, surgical operation, etc. — is a iatrogenic disorder. In particular, ICD-10, includes the followings subsections:

— accidental overdose of drug, wrong drug given or taken in error, and drug taken inadvertently (X40-X44).

— drugs, medicaments and biological substances causing adverse effects in therapeutic use (Y40-Y59)

— misadventures to patients during surgical and medical care (Y60-Y69).

— medical devices associated with adverse incidents in diagnostic and therapeutic use (Y70-Y82).

In our country the "Bases of Legislation of Ukraine on Health Care" is the basic document which regulates the relations between a patient and a medical institution. The law provides a patient's right to choose a doctor, taking into account the doctor's consent. At the ambulatory-policlinic (outpatient) institutions the treating doctor is appointed according to the patient's choice or by the head of the medical institution (its subdivision). In the case of a patient's requirement to replace his/her treating doctor, the doctor must assist in the choice of another specialist. According to the Ukrainian laws, a doctor, on the agreement with the appropriate official, can give up the treatment of a patient, if: "the patient does not follow the medical prescriptions or observe the internal rules of the medical institution, on the condition that this does not threaten the patient's life and the public health. The doctor is not responsible for a patient's health if the patient refuses to follow the medical prescriptions or the regime recommended for him."

The issue of assessing the quality of medical care and the control of its quality (which is even more important) is constantly in the centre of attention of professionals and a wide circle of public. In spite of its seeming simplicity, the concept of *quality* is very hard to define. A univalent criterion of the medical care quality does not exist, because every concrete clinical case requires individual analysis with the participation of experts, careful study of the medical documents, and collective decision-making.

In connection with the possibility of a court claim for the compensation of material or moral damage, the insurance of the medical workers' responsibility becomes important. In accordance with the terms of insurance, the harm caused by the insured person is compensated to the victim by the insurer. The basic laws concerning the citizens' health care provide that medical and pharmaceutical workers have a right to insurance for professional errors which have caused harm to a citizen's health, if the errors did not occur because of careless or indifferent fulfilment of their professional duties. There are also no obstacles for the insurance of the medical and pharmaceutical workers responsibility if their guilt consisted in carelessness. An important aspect of preventing medical errors consists in the need

for the on-going training of the medical staff. Every medical worker is doubtlessly obliged to possess all the knowledge, corresponding to his specialization, rank and position, and to be able to give help in urgent situations. A graduated specialist can not refer to inadequate information or knowledge, and his qualification must fully conform to professional standards. Considering the importance of the protected well-being — human life and health, swift development of the medical science and practice, the issue of the medical workers qualification and experience is important and imposes certain obligations on the health authorities and on every medical worker. Medical workers are obliged to perfect their professional knowledge by reading medical literature, participating in professional conferences and meetings and in different forms of postgraduate training.

THE ROLE OF THE FAMILY IN MAKING MEDICAL DECISIONS

A family is the primary and basic unit of society. It is formed of people which live together, are connected by common way of life, have mutual rights and duties. Family members exert mutual influence on each other in the issues of maintenance and renewal of health, determining the hygienic attitudes, the quality of meals, sexual conduct, psychological climate and attitude toward diseases. A serious disease influences not only the sick person him- or herself, it also violates the usual way of life of all the family members, brings in limitations (economic, first of all), requires particular treatment for the patient, redistribution of duties, compels the family members to change their plans for future and makes them feel worried and concerned. A doctor should be not only a good diagnostician and internist but also be educated in psychology, pedagogy, sociology and cultural issues. It is necessary for him to help the family members to adapt to the situation, teach them how to take care of the patient, give them a correct orientation in the questions of treatment. From the moment the disease begins, the person who has fallen ill begins to act a new part in the family — "the role of a patient", which implies certain rights and duties. It is assumed above all things that a patient must use all his strength and make all possible efforts to get better as quick as possible and to free the family from the financial burden and redistribution of duties.

A patients' personality is complex, it differs from a healthy person's considerably and requires a special approach both from the doctor and from the family members. Mutual relations in the patient-family and pa-

tient-doctor systems to a great extent depend on the patient's attitude to his/her disease. It is this attitude toward illness which becomes a "prism" through which a patient views the world.

The duty of a patient's family is to render him/her help, support and care and to call in the medical workers. The reaction to the development of a disease depends on the severity and course of the process, on the family members' knowledge about the illness and on the existing prejudices. A sudden onset of illness leaves no time for the family to adjust. The initial stage of reacting is characterized by worry, anxiety, and search for the most competent doctor from the point of family members and other people's view. Often the family members have an aggressive and hostile attitude toward the medical workers, thinking that many of them manifest carelessness, extortion or prejudgment. Some patients with specific personality traits are inclined to simulation and aggravation of their symptoms. The more serious and dangerous is the disease, the more the usual mode of domestic life changes, and the more intensive is the relatives' reaction. The patients and their relatives need truthful and objective, and at the same time carefully weighted information. In the contacts with a patient's family the medical workers should remember that not only the patient but also his/her family members need support or even psychotherapy.

The tasks of a doctor who works with a patient's family consist in the following: 1) to formulate a correct picture of illness; 2) to help the family to transform its life in the new situation, to stimulate the reactions of adjustment; 3) to promote the patient's participation in the life of his/her family and to prevent his/her improper behaviour.

Relatives and close friends have substantial influence on the sick member of the family in making medical decisions within the limits of the generally accepted bioethical hierarchy of standards. According to this hierarchy, in the cases when the patients are competent, i.e. able to make decisions, the moral requirement consists in receiving their informed consent to the implementation of the medical interference. However, the standard of informed consent can not be applied to patients, which are incompetent at the present moment, and consequently are unable to make responsible decisions. In cases when a patient was competent before the onset of the disease, a medical decision can be made on the basis of the "*substitute judgement*" standard, if there is convincing information in its support. A substitute judgement is a judgement concerning the patient's probable choice in this situation, if he/she was competent. If a patient was never competent for the reason of his/her child age or a serious mental disorder, and in the cases when a patient was competent before, but there is no clear information on what would his/her wish be in these specific circumstances, the

observance of the principle of respect toward autonomy (present or former) should be found impossible. Medical decisions should be made for such patients on the basis of the "best interests" standard. Taking into account everything that was mentioned above, the hierarchy of medical decision-making standards has the following structure:

1. Informed consent.
2. Substitute judgement.
3. The patient's best interests.

In this hierarchical structure the patient is in the centre of medical decision-making, and this situation is instrumental in overcoming paternalism, characteristic of the traditional medical ethics. Either the patient gives his/her informed consent, or an attempt is made to define what the patient would like to be done, or other people try to establish the best interests of the patient.

If such a hierarchy of medical decision-making standards is used, a conflict can occur between the interests of the patient who occupies the central position, and the interests of his family. At least in some cases of medical decision-making the interests of the patient's family must be taken into account in the moral estimation of the clinical situation. In the ethical solving of such difficult cases an important role belongs to the people engaged in the process of decision-making, first of all to the patient's doctor. Discussions on the necessity of taking into account the interests of the patient's family in making medical decisions are at the initial stage, but it is clear that the exceptional orientation at the patient is not ethically blameless. A doctor must look into the rightness of his/her actions more closely in the followings situations:

1. How should he act when a doctor's duty to respect a patient autonomy contradicts the patient's moral obligations in relation to his/her family members?

2. Should a doctor try to protect a patient from the influence of his/her family and close friends in the process of medical decision-making?

The following example illustrates the conflict of interests of an incompetent patient and the members of her family, which make the medical decision for her. An elderly patient with a progressing mental disorder and other concomitant serious pathology, which can cause the fatal outcome, is hospitalised to an inpatient department. Her husband is against the intensive treatment of his wife, because he is interested in getting rid of the financial and emotional burden and wants to build a new family. Although the husband's moral position of is not blameless, we should agree that the standard of "substitute judgement" is excessively oriented at the patient in the cases when a patient, his/her family members and other interested parties have conflict interests.

THE PRINCIPLE OF CONFIDENTIALITY (THE MEDICAL SECRET)

The principles of veracity and informed consent provide the openness of partners in the social co-operation — the doctors and patients, and the principle of confidentiality is designed to protect them from unauthorized encroachment from outside. The information about a patient, which is given to the doctor or which the doctor gets as a result of medical investigations, can not be passed to a third person without this patient's permission.

The ethics of confidentiality is closely associated with the principle of fulfilling the undertaken commitments, keeping contracts and promises. The ethics of Hippocrates and the ethical codes not based on the Hippocratic traditions have a different attitude to the issues of observing the confidentiality of medical information about a patient. Each of these two ethical systems allows to open certain medical information in some cases and forbids to do so in other cases. It is important to get a clear idea of the essence of these distinctions.

The Hippocratic Oath says, that a doctor must hold back the information "which on no account one must spread abroad". Such formulation assumes that some information can be divulged and even must be divulged. Thus, the traditions of Hippocrates can not be considered as requiring absolute observance of the confidentiality of medical information. The determination of things which can be "spread abroad" is based on the main principle of the Hippocratic ethics: to do good to the patient and to inflict no harm. If the observance of the confidentiality of medical information serves to the patient's good, it must be kept. However, if the violation of confidentiality will answer the principle of help and support to a greater extent, a doctor must expose such information. This approach has distinct paternalistic basis and it was preserved in a number of professional ethical codes which were created in the spirit of the Hippocratic tradition.

Ethical codes which are not connected with the Hippocratic traditions contain other, stricter requirements concerning the respect of the principle of confidentiality. They forbid to divulge medical information, even if there are grounds to suppose that its exposure could be useful for the patient. The theoretical basis of the alternative to the Hippocratic ethics is the *ethics of respect toward personality* which includes four principles. The first is the principle of fidelity — fulfilling one's commitments, keeping promises and contracts. Each person who feels moral obligation to keep his/her promise, even if the consequences will not be the best, follows this principle. The second principle of the ethics of respect toward personality is the principle of autonomy, from which the requirement of informed consent issues. The third principle is the principle of veracity, which presupposes one's

duty to tell the truth. The fourth principle of the ethics of respect toward personality consists in the necessity to avoid killing people, which the supporters of euthanasia should take into account.

From the perspective of the ethics of respect toward personality it is necessary to consider confidentiality in the context of the principle of fulfilling one's commitments, keeping promises and contracts. This principle includes a wider circle of ethical norms than just the patients' good. A doctor's commitment to keep the medical information confidential is a part of his duty towards a patient. When a relationship is formed between a doctor and a patient the promise of confidentiality is presupposed. Therefore a doctor must keep this promise and not violate confidentiality proceeding from the motive of the patient's good. The ethics of respect toward personality is a variant of ethics based on one's duty. It differs from the ethics of utilitarianism, which is oriented at creating good consequences and avoiding bad ones. While the utilitarians determine the moral justification of actions by analysing their consequences, the ethics of respect toward personality recognises certain behaviour simply as the performance of one's personal duty — regardless of its consequences. If an action involves the breach of promise, lies and disrespect toward autonomy, it is morally wrong according to these signs, even if its consequences are good. Such ethical concentration on the internal nature of an action, its structure or form is sometimes considered to be formalism. According to this point of view actions are correct or wrong not for the reason of their consequences but for the reason of their internal content or form. Some actions are simply one's personal duty (*deontology* is the science about due conduct), regardless of their consequences. Formalistic and deontological approaches to ethics, as, for example, the ethics of respect toward personality, are the leading alternative to ethical systems (including the traditions of Hippocrates), which decide what is or is not morally acceptable on the basis of the nature of the consequences of actions.

In the modern Western society bioethics there are steady tendencies to make an accent on formalistic and deontological codes, in which the term "rights" is used more frequently than "duties", although there is close relation between these concepts. If, for example, a patient has a right to confidentiality of medical information, other people in this case have a reciprocal duty to avoid disclosing the information concerning this patient to a third party.

The movement of the modern generation of bioethics from the Hippocratic paternalism, based on the utilitarian principles of beneficence and non-malfeasance, to the ethics based on obligations (duty), including the ethics of respect toward personality with its principles of fidelity (keeping promises), autonomy, veracity and maintenance of life, — makes an important vector of biomedical ethics development in late XX-th — early XXI-st centuries.

Paternalism, as an action undertaken for another person in the name of his well-being, but against his will and consent, is more and more criticized by the medical ethics including the field of the principle of confidentiality. The basic idea of the fidelity principle as a component part of the ethics of respect toward personality in the doctor-patient relations is mutual loyalty. Ethical complications arise in the cases when the fulfilment of agreements and promises is not the method of providing of the best consequences for the patient. The consequences push the doctor toward one action, while the obligations — to another. The fidelity principle grounds an independent duty to act up to promises and fulfil contracts. Such principles are characteristic of the classic ethics of Judaism and Christianity, they were transferred to E. Kant's secular ethics and to other formalistic and deontological ethical systems, according to which one must keep promises (including the promise to observe confidentiality) simply because such promises were given.

It is interesting that in the Declaration of Geneva, which on the whole is expounded in the traditions of Hippocrates (and is therefore named the XX-th Century Hippocratic Oath) diverges from the original text in regard to the principle of confidentiality. It firmly insists on the confidentiality of the medical information and contains no exceptions.

Some ethical codes diverge from the traditions of the Hippocratic Oath still more, and presuppose the possibility of disclosing confidential information not for the patient's good, but in order to protect others from serious danger and harm. For example, the British Medical Association considers that confidentiality can be broken in accordance with the provisions of law or when a doctor has superior obligations toward the society. Depending on the legislation, such exceptions can include the legal duty to report about wounds inflicted by firearms and plain weapons, venereal and other infectious diseases, or the diagnosis of epilepsy. In these cases the doctor's duty consists in explaining the reasons for these exceptions to the patient.

Many kinds of medical ethics consider the duty of respect toward confidentiality (in all its importance) only as one of the conditional (*prima facie*) obligations, which sometimes are justified, and sometimes — overcame in the conflict with other obligations. All the complexity of the moral dilemma for the medical specialists in the situation of conflict of interests as it applies to the problem of confidentiality is reflected in a case, which got a wide fame among the public, medical professionals and the bioethics in the USA (the case of Tarasoff). The essence of this conflict consisted in the moral choice made by a psychiatrist, who had found out that his mentally ill patient intended to kill a young woman. The psychiatrist decided to observe the confidentiality of the medical information, did not disclose the patient's criminal intentions to anyone, and the murder was committed as a result.

Was the psychiatrist obliged to share this medical information with a third party and by doing so prevent the harm, which could be done to another person or society? If yes, does this obligation prevail over his duty to respect a patient's confidentiality? The judge's decision consisted in giving positive answers to these questions. Answering the claims of the defence concerning the importance of the principle of confidentiality in the psychotherapeutic practice, the judge specified that public interests in security had a greater weight in comparison to the patient's right to private life.

In the "Bases of Legislation of Ukraine Concerning Health Care" article 40 ("The Medical Secret") is devoted to confidentiality. The use of the term *medical* (in Russian — *doctor's*) is justified by tradition, but it is not quite precise. It concerns the obligations of doctors, as well as all the other medical and pharmaceutical workers and officials, who receive the medical information in accordance with the law.

The objects of confidentiality include the diagnosis of the disease, the information concerning the state of health, the prognosis and all the data received by a doctor in the course of a patient's investigation. The non-medical information concerning a patient or his family, which becomes known to the doctor in the process of his official duties implementation, must also remain confidential. The laws define a narrow enough circle of situations in which a medical worker has a right to share the information known to him with third parties. Firstly, this concerns the cases, when a patient is unable to express his will independently because of the disorders of consciousness or for the reason of child age. In the last case an age limit of 15 years is established. The medical information on the state of health of adolescents more than 15 years old can be given to the parents or other persons only on the teenagers' consent. The law also limits the action of the confidentiality rule if there is a threat of infectious diseases being spread, mass poisonings or other mass affections. Same as the laws of other countries, the "Bases of Legislation of Ukraine Concerning Health Care" permit the violation of confidentiality if the doctor has grounds to suppose that the patient's illness is a result of unlawful actions. Wounds inflicted by firearms or plain weapons can serve as examples. The legislation is founded on the base of certain moral qualifications of human actions, distinguishing what is "good", what is permissible, and what is "very bad" and can not be tolerated in this society. It establishes the minimal level of moral regulations, which must concern all the citizens with no exceptions. Moreover, separate citizens and certain social groups have a right to set their own higher level of moral requirements. This remark fully concerns the medical profession, within the framework of which the rule of confidentiality has a special value, in spite of substantial cultural and ideological distinctions.

Confidentiality between a doctor and patient is desirable, as it confirms and defends another, more fundamental value — the inviolability of private life. Only the guarantee of absolute observance of confidentiality by the medical workers allows the patient to be frank enough, without fearing that the inviolability of his private life will be somehow violated.

The principle of confidentiality is also an important condition of the protection of the patients' social status. A medical diagnosis or other medical information can become a stigma for a person and considerably limit his/her possibilities for social self-affirmation. The information concerning a mental disorder, the HIV-infection, a malignant tumour, a genetic vice, homosexual orientation, a venereal disease, or a sexual disorder, which a patient suffers, can cause his/her social isolation and directly threatens his/her social status.

The rule of confidentiality protects the patients' economic interests too. The information about the presence of an oncologic disease even in its curable form can considerably limit the possibilities of the patient's promotion or being elected to an official position. The disclosure of the information that a psychiatrist or a lawyer are HIV-infected can sharply reduce the number of their clients, and thus inflict a substantial financial damage, although in reality their virus infection bears no serious threat to the clients.

Confidentiality in the relations between the professionals and their clients is necessary to provide frankness of their communication. A patient who uncovers him- or herself before a doctor both in the direct and figurative sense must be sure that this will not cause undesirable consequences. Only the patients' confidence in the absolute observance of confidentiality provides frankness, which is essential for the medical workers' normal professional activity. By protecting confidentiality a physician protects not only his patients' but also his own personal interests. A doctor's image in the eyes of the society and his popularity directly depends on his ability to provide the confidentiality of information concerning his patients effectively. The modern legislation in the field of health protection provides a patient's right to choose a doctor and a medical institution. In the situation of choice the preference will naturally be given to a doctor who, besides his high professional qualities, demonstrates his correspondence to high enough moral standards, in which the observance of confidentiality acts a very substantial part.

By effective protection of confidentiality, medical workers provide trust in the relationships with their patients. The concept of trust is wider than the concept of frankness. For example, being at a hospital, a patient can find himself in a situation when because of an unfavourable development of a disease or as a result of a medical manipulation, the control over his state will be fully in the doctors' hands. A patient should trust the doctors and believe that in all such situations they will observe his interests.

The observance of the rule of confidentiality is very important for the realization of a patient's right to autonomy, which to some extent adjoins with the protection of his private life inviolability and the necessity to guarantee his/her social status and economic interests. However, the right to autonomy has a more general nature. The point is that in principle a human being feels him- or herself a valuable, responsible and self-regulating person only when he/she is able to control the events of his/her life effectively. Herein is the guarantee of his/her personal freedom, minimal dependence on external forces, which aim at manipulating his/her behaviour. The disclosure of the medical information makes a person more vulnerable and dependent in this aspect.

As it was mentioned above, with all the importance of observing the rule of confidentiality for the maintenance of a due standard of medical activity, there are a number of situations in which its application is problematic. One of the most sharp disparities arises in the cases when the medical information about the patient concerns the vital interests of third parties — his/her relatives or people, with whom the patient is in contact while implementing his professional or other duties. Situations which arise in genetic testing can serve as a characteristic example. The diagnosing of a symptom, indicative of the presence of a gene which determines or predisposes the patient with a high degree of probability to the development of some serious pathology, has substantial importance not only for this patient but also for his genetic relatives or his/her spouse. A patient is not always inclined to share such information with his/her relatives, although it could protect them from a serious danger. A doctor's professional duty consists in doing everything possible to prevent every danger to other people's health, of which he knows. At the same time, the rule of confidentiality obligates him to follow the interests of a concrete patient and abstain from disclosing the information without his consent. A conflict of values arises, which can not be settled in a simply mechanical way.

How should such conflicts be resolved, when they arise in real practice? First of all, the situation must be discussed with the patient in details. In a number of cases it is useful to discuss the situation with colleagues (which, having got this information, are also limited by the norm of confidentiality). Sometimes a patient's disagreement to share information is conditioned by the fact that he either underestimates the seriousness of his state or exaggerates the difficulties which he can encounter after the disclosure. In the cases when the attempts to convince a patient fail, the doctor must make his own decision and bear all the load of responsibility for it. There are no ready recipes for all cases of life. One thing is clear: if a doctor is morally mature, if he has experience in solving and discussing similar situations, and if he is acquainted with the experience of his colleagues, his choice will be more responsible and morally grounded.

Substantial problems for the realization of the confidentiality rule arise in connection with the progressing division of labour in the medical practice. If earlier a doctor could carry out a patient's treatment alone and could personally control the information, in a modern policlinic or hospital the work with a patient is done by dozens of people — doctors of different specialities, nurses, administrators, technicians, laboratory assistants, and social workers. So confidentiality became not only a doctor's moral quality, it concerns all the medical collective. It is also necessary to consider the rapid computerisation of the storage and processing of the medical information, which on one hand greatly improves and facilitates this process, but on the other — creates a new possibility for unauthorized access to the medical documents. The issue of confidentiality has grown into a problem concerning the reliability of the modern social and technical systems, which involve separate medical workers, medical collectives and computer-based informational systems.

A serious problem in the practical realization of the rule of confidentiality is caused by a steady tradition of our domestic doctors not to extend the prohibition of disclosing confidential information to the members of the patient's family. Moreover, in the cases when a malignant oncologic disease is diagnosed or the prognosis is unfavourable for the patient's life, it is his family that usually receives the reliable information, which is concealed from the patient. From the point of bioethical canons such a position is not admissible. Bichamp and Childress ask a question: "What right does a doctor have to begin with disclosing the information to the family without the patient's permission? The families help to provide the necessary care and support to many patients, but an autonomous patient has a moral right to impose a veto on any attempt of intervention on the part of his/her family." The discussion of the medical information with a patient's family members behind his/her back should be considered a violation of the rule of confidentiality.

When beginning to question and examine a patient, a doctor should ask him in a tactful form to what social and cultural group he belongs, and whom does he authorise to have access to the information concerning his health. In a normally functioning family a husband or wife usually are the natural trusted persons for the patient, and he/she usually delegates the authority to the spouse, but if the family is unstable, the patient can choose someone else (his/her parent, a close friend) as the trusted person. The representatives of some religious communities can select the priest as the trusted person. It is necessary to take all these aspects into account when following the principle of confidentiality.

The violation of the principle of confidentiality is a criminally punishable act. In the Criminal Code of Ukraine article 145 concerns "Illegal disclosure

of the medical secret". It says: "Intentional disclosure of a medical secret by a person, who got the information while executing his professional or official duties, if this act entailed serious consequences — is punished by a fine up to fifty minimums of the citizens' not taxable profits, or by social works for within two hundred forty hours, or by deprivation of the right to hold certain positions or executing certain activities for within three years, or correctional works for within two years".

There are distinctions between the concepts of confidentiality (medical secret) and private life. The inviolability of private life is observed when other individuals do not intrude into the personal sphere without permission and do not get access to intimate and delicate information, which a person does not want to share with anybody, or is ready to share it only with a narrow circle of people. Thus, the delicate medical information belongs to the field of private life; the patient allows the doctor and other medical professionals to get access to its details and does not consider this to be an interference with his private life. However, unauthorized access to this information of other persons would undoubtedly be a violation of the inviolability of private life. While the inviolability of private life does not allow other persons to intrude into an individual's private sphere without permission, confidentiality concerns the obligation of the people, who have a legitimate access to private information, to abstain from spreading it. Illegal access of other persons to the information concerning the private sphere of life is considered a violation of the inviolability of private life and is also pursued by law. Article 182 of the Criminal Code of Ukraine "The Violation of the Inviolability of Private Life" says: "illegal collecting, storage, use or spreading of confidential information about a person without his consent, or spreading this information in public presentations, in a work, demonstrated in public, or through the mass media — are punished by a fine up to fifty minimums of the citizens' not taxable profits, or by correctional works for within two years, or an arrest for up to six months, or by limitation of freedom for within three years."

Section V
BIOETHICAL ASPECTS OF DYING AND DEATH

"Time to live and time to die."
Ecclesiast

THE DEFINITION AND CRITERIA OF DEATH

At the end of the XX-th century the human attitude toward death has changed. Earlier death was considered a natural end of life. Many diseases were incurable, the average life span was small and the infantile death rate was high. By the end of the XX-th century the progress of medical technologies prolonged the life-span often in combination with its acceptable quality. A popular opinion appeared on the possibility to slow down the senescence and postpone death. People frequently die not at home but at inpatient institutions and hospices, where patients receive emotional, spiritual and medical support. On the other hand, there is an ethical opinion that the control of pain and distress at dying apparently can be best provided by the completion of the personal life.

Cases of considerable worsening of the life quality as a result of the application of new technologies, which prevent a patient from dying, became a serious ethical problem. It became necessary to solve the questions concerning the ethical acceptability of abstaining from sustentation therapy or its stopping. If this tactic it permissible, what is its difference from euthanasia and what is the ethical estimation of euthanasia? An additional impulse to the ethical debates concerning dying and death was given by the intensive development of transplantology with the necessity of getting donor organs.

Many of the mentioned ethical problems are directly connected with the definition and criteria of death, and also with the development of tests which allow to establish the fact of death. The definition of death is a mainly philosophical task, the development of the criteria of death — a

mainly medical task, and the choice of tests to confirm these criteria — an exceptionally medical task.

From the world outlook point of view, an object to which the terms of life and death are applicable is an organism as a whole. An organism is alive while the integrated activity of the cardio-vascular, respiratory and central nervous systems goes on. An organism dies when the integrated activity of these three systems ceases finally. Permanent loss of any "corner" of this triangle soon results in the permanent loss the other two. Death is the moment when the physiological systems cease to operate as a united whole, even if life proceeds in separate cells or organs.

Death is the permanent cessation of the organism functioning as a whole. This functioning is understood as spontaneous integrated activity of all or most subsystems (for example, the endocrine control), and at least a minimal level of response to external influences (for example, to the changes of temperature). The activity of certain subsystems can be artificially replaced (an artificial driver of the heart rhythm, artificial lung ventilation) without the change of the status of the organism as a whole. Consciousness is an inalienable human characteristic. If it is lost, life loses its sense.

The philosophical and bioethical analysis of the attitude toward death, which was carried out at the end of the XX-th century resulted in an unexpected conclusion on the absence of an adequate definition of death, or more precisely, the absence of such an exact theoretical definition of death, which could be successfully used in different practical situations. For many millenniums physicians used traditional concepts to establish death: the cessation of heart activity, the cessation of breathing and insolvency of other functions of the organism. The inaccuracy of this determination consisted in the fact, that the death of these few organs was equated with death of all the organism. This error became especially noticeable, when by the end of the XX-th century the medical technology became capable of supporting the autonomous activity of almost every separate organ for long periods of time (including those two especially important ones, the cessation of the functioning of which was considered a convincing sign of death — the breathing and heart activity).

The essence of the mentioned philosophical and bioethical problems is based on the imperfection of the *medical criteria of death*. From the principle positions permanent loss of cardio-respiratory functions and complete and irreversible loss of all the brain functions can be selected as such criteria. Due to the use of modern instrument technologies which allow to support vital functions for long periods of time, the permanent loss of spontaneous breathing and blood circulation can not serve as an obligatory indicator of non-functioning of the organism as a whole. It would be absurd to consider that the patients incapable of independent breathing because of the

paralysis of respiratory musculature after poliomyelitis, or the patients with asystolia, who require the implantation of a heart rhythm driver, are dead. It could be suggested to use permanent absence of not only spontaneous, but also artificially supported functions of breathing and blood circulation as the criteria of death. But on the other hand, with the artificial support of breathing and blood circulation the organism can cease functioning as a whole long before the lungs and heart stop their artificial functioning. Thus, the lungs and heart do not have the unique relation to the functioning of the organism as a whole. A patient supported by artificial lung ventilation with a totally ruined brain is a "preparation" of artificially supported subsystems rather than a person.

Permanent and irreversible loss of the activity of the entire brain correlates with the cessation of the functioning of the organism more precisely. This criterion has traditional historical parallels: the doctor invited to certify death always paid attention to the absence of response, absence of spontaneous movements, including breathing, and the absence of the eye papillary light reflex in the dying patient. Such a symptom as the absence of heart activity does not have direct relation to the cessation of the entire brain functioning. The criterion of the "brain death" was offered in the early 1980-s. The new criterion was theoretically based on the circumstance that the brain, unlike the respiratory or blood circulation organs integrates the work of all the other organs of the body and is responsible for the work of consciousness. Therefore, the error of equating the death of one organ with the death of all the organism does not concern the brain.

In 1968 the clinical criteria allowing to define "technically dependent" patients with a complete cessation of the entire brain functions, including the primitive brainstem reflexes, were presented in the report of the Harvard Medical School committee. The committee suggested to name them "patients in the state of irreversible coma", recommended to consider them dead and to stop artificial respiration support. In accordance with the Harvard criteria, patients in the state of irreversible coma were designated as patients with the brain death. However, the case description of patients in the permanent vegetative state promoted the debates on the question whether it is rightful to consider patients in the protracted unconscious state dead. In such people some functions of the brainstem remain, which regulate their breathing, blood pressure and a number of other vegetative functions. In spite of the absence of the brain cortex functions, such patients can breathe and their cardiac activity continues even without "technical support". They have no consciousness, but they go to sleep and wake, preserve independent breathing and brainstem reflexes. These patients are unable to chew, swallow and react to pain adequately. Such a state can last for different time — from a few days to many months and even years. Taking into account complete

dependence of such patients on medical care and the necessity of their permanent very expensive medical support and long-term observation, a question arises about the nature and justification of their protracted active therapy and even the maintenance of their life. The Harvard criteria imply that death means the cessation of the entire brain functions, whereas the patients in the permanent vegetative state can not be considered dead, because the function of their brainstem continues. Nevertheless, many specialists in bioethics recommend to consider such people dead. In their opinion, a dead human being differs from a living one by complete and permanent loss of consciousness, rather than complete and permanent loss of the entire brain functions. This contradiction in fact reflects the distinctions in the views as to how exactly we imagine an individual who can be considered dead. What exactly ceases to exist, when we agree that a person has died? It is a difficult, inevitable philosophical question produced by the possibilities of modern medicine to support the vital functions in patients with the full and permanent absence of consciousness. All these pre-conditions became a basis for the new understanding of death as the loss of the brain cortex functions. The supporters of this criterion of death suppose that a personality can be dead even if the *organism as the whole* remains alive. What is important indeed when we talk about life is the proceeding existence of the personality rather than of an impersonal organism.

Tests which are used for the confirmation of death imply the verification of complete and permanent absence of functioning of both hemispheres and the brainstem. They include the absence of response to stimuli (deep coma), absence of the papillary light reflex and the brainstem reflexes, and full apnoe. An isoelectric flat line on the electroencephalogram and the tests documenting the absence of cerebral blood flow for at least 30 minutes confirm death.

In 1968 the Harvard Medical School committee developed and published a number of tests allowing to diagnose the death of the entire brain. In the opinion of the committee, from the moment this state is registered the patient's death should be certified and the support of his/her vital functions with technical means should be stopped. Thus, a patient with entire brain death is considered dead even if his/her breathing and blood circulation can be supported artificially.

It is possible to make a heart, which had stopped, work again and to provide the renewal of brain functions by resuscitation measures, so the stop of the cardiac activity and breathing can not be considered reliable tests for death certification.

Thus, by the present moment three principal conceptions were formulated as to the criteria of death certification — the cardiac death, the entire brain death, and the death of the higher brain.

In accordance with the first conception, a person dies only when the irreversible termination of the blood circulation and breathing functions occurs. A subject can be considered alive, though, even if his/her heart does not function (is "dead") or even if it was removed. This paradoxical situation can be illustrated with the incident which happened to an American dentist Barney Clark at the university of Utah (the USA). While he was waiting for heart transplantation he had an operation of his own heart removal, and his aorta and veins were joint to an "artificial cardiac pump". With such an artificial heart Clark lived for four months. The patient was conscious, sometimes he even got up from his bed and walked. Could anybody, including the supporters of the cardiac interpretation of death, consider Clark dead? Certainly, this case is unusual, but it is quite clear that Barney Clark did not die during this period. It is necessary to stress that the definition of death, which is oriented at the heart, includes the criterion of irreversibility of the vital functions termination. Clinical doctors frequently and probably erroneously estimate the patients who's heart had stopped and after that they were successfully resuscitated as having been "clinically dead". Death means *irreversible* termination of blood circulation and breathing. If a person's heart had stopped, and then he/she was resuscitated, this means that he/she had never died! His organs and tissues continued to live. Potentially we can rescue such a person. A person can die if his cardiac activity stops, and we do not provide cardiopulmonary resuscitation, but it is not correct to say that he had already been dead.

In accordance with the death of the entire brain conception an individual is considered dead when the functions of his/her entire brain, including the brainstem, cease irreversibly. This conception is based on the belief that the essence of a human being consists in his/her capacity for the corporal (physical) functions integration. And, as it is assumed that the brain controls this integration, a human being can be considered dead only when the functioning of the entire brain irreversibly ceases. The death of the entire brain conception is the generally accepted legal base for the certification of death in the majority of countries, except for some Asiatic countries, where this conception conflicts with the traditional perspectives of Buddhism.

Finally, the conception of the death of the higher brain can be applied to the situation, when a patient is in an unconscious state, the majority of the brain functions are lost, but certain brainstem reflexes remain intact. In accordance with the conception of the death of *the total* brain, he can not be considered dead, until *all* the brain functions will not cease. At the same time, in accordance with the conception of the death of the higher brain, such a patient can be considered dead, if the higher functions of his/her brain are permanently absent. The points of view as to which functions should be selected as critical in this situation are contradictory. Some spe-

cialists consider that the cortical functions are most important. In theory, however, some motor functions of the brain cortex can remain, while all the sensory functions are completely lost. Some supporters of the death of the higher brain conception equate death with the irreversible loss of consciousness and cogitative functions. The clinical situation in which the higher regions of the brain are irreversibly damaged, while the brainstem remains intact and the lungs and heart function without artificial support is defined as *the permanent* or *stable vegetative state*.

The definition of death and its criteria can not be considered perfect and need further revision, because the introduction of the new criterion of the death of the whole brain (or its higher regions) as an integral organ does not solve the basic problem: the reduction of a human being to an organ. The critics of the existent criteria of death point out that in some poisonings or deep super-cooling the encephalogram also registers the cessation of the brain functions, which can be restored later. The specialists have realized that the search for a more adequate criterion of death must proceed in the direction of a yet more integral and generally recognised criteria. By the way, such integral criteria are offered and discussed: capacity for communication, capacity for the response to stimuli and, finally, sensitivity to pain (suffering) or pleasure. Today it is still hard to define what the eventual result of the undertaken efforts will be: a general criterion of death (or life) has not been elaborated yet, and discussions continue.

The Harvard Medical School committee suggested the following unified definition of death: "An individual, who has suffered either irreversible cessation of the functions of breathing and blood circulation or irreversible cessation of the functions of the entire brain, including the brain stem can be declared dead".

It is indicated in the Declaration of Sydney of the World Medical Assembly (1968)* that "death is a gradual process at the cellular level with tissues varying in their ability to withstand deprivation of oxygen. But clinical interest lies not in the state of preservation of isolated cells but in the fate of a person. The point of death corresponds to the irreversible cessation of the integrative functions of the brain, in particular the brainstem functions. However, no single technological criterion is entirely satisfactory in the present state of medicine nor can any one technological procedure be substituted for the overall judgment of the physician. Determination of the point of death of the person makes it ethically permissible to cease attempts at resuscitation and in countries where the law permits, to remove organs from the cadaver provided that prevailing legal requirements of consent have been fulfilled."

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* http://ethics.iit.edu/codes/coe World_Medical_Association_Declaration_of_Sydney_1968.html *(the translator's note)*

In the documents which regulate the criteria of death, adopted in different countries, death is determined both according to the traditional criteria (cessation of heart activity and independent breathing in the absence or ineffectiveness of resuscitation or its late beginning, incompatible with the rehabilitation of the brain) and according to the criteria of actual brain death with continuing heart activity. Thus, the brain death is an irreversible, determined by global destruction of the brain tissues cessation of the brain-provided ability to contact with the environment, to react to external influences and to control the basic vital functions — independent breathing, blood pressure and homeostasis. Consequently, an organism in the state of brain death is doomed to death in the traditional understanding (cessation of heart activity) within the limits of the nearest few days or weeks. The diagnosis of brain death, taking into account its equivalence with the death of an individual, serves as grounds for stopping life-supporting therapy — artificial lung ventilation and using medicines which support the blood circulation. From the moral and ethical point of view, the decision on stopping this therapy must be made by the treating doctor-resuscitologist after a discussion with collegues; however, nobody has a right to force him to stop these measures, as well as he can not force his inferiors to do it. Probably, a doctor has a right to limit the therapy, this soon will result in the cessation of heart activity. In the cases when the artificial lung ventilation and the use of medicines which stimulate the blood circulation were stopped, it is not necessarily to inform the relatives about this.

It is important to stress the role of bioethics in the development of the philosophical conception of death and its criteria. The most important issue which is discussed in relation to death is the question: what does it mean to be a human being, to be a personality? The discussion of this problem with the use of medical and biologic materials showed that such attributes of life as health, biological parameters of the organism, the activity of separate organs and even the brain functioning do not help to define the concept of personal life, the life of a human being. When we speak about the human life, we stress that it can not be reduced to breathing, heartbeat or digestion (although without them life is impossible). In fact, such biological life does not have a quality of the life of a *personality*, and if it does not have this quality, it is not a real life in the human sense of this word. Many people consider such a prospect of reducing all life to its biological aspect as something worse than death. Therefore they point out that in the fear of death we should be afraid not of death as such but of this biological, "vegetable" state from which it is desirable to deliver and rescue oneself, even if such rescue would mean death or self-destruction. In this case the right to death means care about the human dignity, and the protection of this dignity can be more important than death. This is an ethical idea: death is considered

not as the most frightful event that can happen to a person: the loss of one's dignity, the loss of oneself is worse.

Another important feature of the new criterion of death (the brain death) is that death (as a medical fact) was for the first time considered not as an instantaneous event but rather as a *process*, consisting of several stages — the cessation of breathing and heartbeat, cessation of brain activity, and the destruction of cells in the organism. This division of death into an act and process was not only practically important but also theoretically fruitful: the philosophical development of this division began. In the concept death two meanings were differentiated: death as an event, i.e. the result of the process of life cessation, transition from being to non-existence as the fact of non-existence; and death as a process preceding this event as the transient state between life and death — dying. First this division was analysed in the work of Elizabeth Kubler-Ross "On Death and Dying", first published in 1969. The clarification of these concepts was important, because their use in different meanings resulted in confusion: when we speak about the fear of death, we mean not the non-existence but being afraid of dying, when we are still able to feel pain and to suffer, and sometimes to realize our own dying.

The specialists in bioethics, medical workers and lawyers pay special attention to the process of dying, i.e. the interval in which the human consciousness directly encounters the fact of personal death, gets acquainted with it, and either struggles with it or submits to it, but in both cases suffers painfully. If we consider the fact that these sufferings at times last for a very long time and sometimes become unbearable, there follows a logical conclusion as to the desirability and possibility of their quickest stopping. The concentration of bioethics on this period of passing from life to death is quite understandable: the modern medicine is at such a stage of its development when it still can not cure a great number of illnesses but disposes of facilities to support the state of chronic illness for a long time, so that the majority of people (according to the WHO data — over 70%) die not suddenly but gradually. The sufferings experienced at this time are not only especially painful, but they also seem to the majority of people (in connection with the weakening of traditional beliefs) to be quite senseless, and thus unnecessary. So gradually a new understanding of the meaning and value of such a state of life developed. If earlier life (in general, as such) was considered the highest value and was surely preferred to death, now the question is asked in a different way: is every life in its any state indeed better than death? The principle of respect toward autonomy suggests that it is ethically correct to let the patient decide what attitude should he choose toward his/her own death. As a result a substantial ethical clarification was introduced to the concept of death — the right to death, i.e. the recognition

of a person's highest authority in the issues concerning his/her life and death. The right to death was officially registered in a special document — "the will of life" (testament), which every person in the state of complete consciousness and necessary mental capacity can make (but also can revise it) in relation to voluntary renouncement of special facilities of extension of his/her life and life-supporting treatment in the case of irreversible and incurable disease.

Thus, if in traditional medicine, classic morals and the European legal field the main principle of attitude toward death was to fight against it, in the context of bioethics attempts were made to "rehabilitate" death, to revise the purely negative attitude toward it in the cases when something even more frightful than death can await for a patient.

BIOETHICAL PROBLEMS OF EUTHANASIA AND SUICIDE WITH A DOCTOR'S ASSISTANCE

In the bioethical analysis of the problem of death attention, foremost, is concentrated on the process of transition to death, on dying, which can be long and painful. This period was selected as the major aspect of death. The problem of euthanasia as well as all the discussions round it should be considered in the context of the method (which is unique for the time being) to overcome the fear of the period (and process) of dying. This is the essence of euthanasia: there are no other facilities to rescue a person from the painful *process* of dying, when the patient and all the other people around him know that he is dying, but nobody can render him effective help.

Euthanasia (in the translation from Greek — a rapid and easy death) is an intentional acceleration of death, or killing an incurable patient, who is in a terminal state, with the purpose of ceasing his/her sufferings. The authorship of the term "euthanasia", in the opinion of most specialists, belongs to the English scientist Frances Bacon, who wrote: "A doctor's duty consists not only in recovering health but also in alleviating sufferings and torments, caused by illness, and this not only in the cases when such alleviation of pain as a dangerous symptom can result in recovery but even in the cases when there is no faintest hope for rescue and it is possible only to make the death more easy and quiet, because this euthanasia... is a considerable good fortune in itself."

The term "euthanasia" is used both in a narrow and in a wide sense. The distinctions are most clearly visible in the clarification of the concept of

"killing" and in the consideration of distinctions between two non-equivalent semantic tints: to "kill" or to "let die." If we use an analogy with a drowning person, the distinction between "killing" and "letting die" is the same as between "drowning" someone and "failing to rescue a drowning person", "letting him drown." It is known that from the legal point of view only the first act is characterized as murder, while the second one is only a subject of ethical estimation.

In the narrow sense "euthanasia" is limited by active operations, which accelerate a patient's death. In this context the question concerns murder motivated by humane considerations. An injection of a lethal dose of a drug to a terminal patient with the purpose of alleviating his intensive suffering is an example of such understanding of euthanasia. On the other hand, actions which "let the patient die", such as withholding, or stopping the life-supporting treatment, are not considered as euthanasia in the narrow sense of this concept. Although the term "euthanasia" is more often used in its narrow meaning, its interpretation in the wide sense is also possible, when euthanasia unites both killing and letting die (on the basis of humanitarian considerations). If we use the concept of euthanasia in a wide sense, it is didactically justified to make distinctions between active euthanasia (i.e. killing) and passive euthanasia (i.e. showing mercy by letting a patient die).

Another difference is also very important in a discussion of euthanasia. *Voluntarily* euthanasia is carried out in response to an informed requirement of a capable patient. *Non-voluntarily* euthanasia implies cases, when a patient is not able to give his/her consent to it because of incompetence. The possibility of such euthanasia is considered in the patients who are unable to make independent decisions (for example, the mentally ill).

If we examine the whole complex of cases of voluntarily/non-voluntarily and active/passive euthanasia, we can distinguish the following four varieties of euthanasia: 1) voluntarily active; 2) non-voluntarily active; 3) voluntarily passive; and 4) non-voluntarily passive. Modern debates focus, foremost, on the moral legitimacy of voluntarily active euthanasia. A smaller number of contradictions arise concerning the morality of passive euthanasia. The idea of moral acceptability of withholding the life-supporting treatment or its termination is considered grounded enough, at least, in the USA.

During the last years physicians and philosophers, psychologists and lawyers, theologists and politicians, ethics and bioethics are considering the problems of euthanasia deeply. Different medical, biological, ethical, ideological, religious, social, philosophical, and psychological problems are involved in the sphere of euthanasia. The supporters of active euthanasia speak about it as a human right "to dignified death". Some authors stand up for opening special clinics of *"easy death",* other — for the creation of special equipment for suicide.

The story of an American doctor Jack Kevorkyan, known as "Doctor Death" got wide international publicity. Since 1990 he helped approximately 130 terminal patients, who suffered from permanent intensive pains and made conscious decisions to terminate their lives voluntarily, in the execution of their intentions. For his long medical practice he came to a stable belief that a person has a right to dispose of his/her life, and if he decides to die with the purpose of ending his suffering, the task of a doctor-humanist is to help him do this "correctly" and painlessly. Jack Kevorkyan offered the term "patholysis" to denote the suicide of a patient helped by a skilled specialist, and created a special device for this purpose. Quite predictably, after the first experiments of giving this unusual help discussions of "pros and cons" began. In 1999 J. Kevorkyan was convicted for 7 years for executing 131 acts of active euthanasia.

In the attempts to find ethical (and legal) grounds of the acceptability of active euthanasia specialists formulated a concept of "the right to death," which has never been used before. The opinions of this problem vary greatly — from complete non-acceptance of active euthanasia: it can never, in no cases be morally justified, to quite an opposite point of view: active euthanasia is a blessing, it should not only be justified but even welcomed as a delivery from unnecessary suffering. The supporters of more moderate points of view suggest to add clarifications and limitations to each of the extremes, and also to work out the details concerning the control and provision of the patients' safety.

The supporters of the moral recognition of active euthanasia operate with the considerations of humanism. When people support complete and unreserved defence of active voluntarily euthanasia, they appeal to humanism combined with arguments as to the supremacy of individual autonomy. Two basic arguments in the defence of active euthanasia sound as follows: 1) it is cruel and inhumane to refuse the request of a terminally sick patient for putting a "merciful" end to his life in order to avoid further suffering; 2) it is necessary to respect and take into account a person's conscious choice if it does not harm others. Considering that in the cases of active voluntarily euthanasia of terminally sick patients nobody is harmed, an individual's desire to terminate his/her life should be respected and taken into account.

The supporters of active euthanasia suppose that the grounds for its execution include the incurability of disease, unbearable suffering and the patient's informed voluntarily consent to die. Sometimes psychological, mental, age-dependent, moral and economic reasons are added.

Should active euthanasia be legalized? As illegally it is carried out in all the states of the USA, the question of its legalization rose repeatedly in this country (foremost this concerned the voluntary euthanasia). Voluntary active euthanasia is legally practiced in Netherlands. One of the specific as-

pects of the Netherlands system is that active euthanasia can be carried out in the cases when a patient experiences unendurable suffering (which can not be alleviated), and it is not necessarily for him/her to be a terminal patient. Active euthanasia in Netherlands can also be carried out in relation to an incompetent patient if he/she had clearly expressed the desire to die when he/she was competent. The experience accumulated during more than 20 years of active euthanasia practice in Netherlands is an inexhaustible source of information on ethical discussions. There is a steady tendency in the world to support active euthanasia. In 1996 this procedure was legalized in North Australia.

It is assumed that if active euthanasia is legalised, concrete actions on its execution should be carried out by a doctor. However, in principle, this act can be entrusted to other specially trained professionals, and this would have ethical advantages.

The opponents of active euthanasia advance the followings basic arguments to ground their beliefs: 1) an innocent person's murder is a primary evil; 2) murder is incompatible with a doctor's professional responsibility; 3) any systematic acceptance of active euthanasia can result in undesirable social consequences (by diminishing the respect to human life). The last argument is used most often in the discussions on the legitimacy of active euthanasia. Concern is caused by the consideration that if active euthanasia is allowed, many new reasons for it will be found sufficient and the number of candidates to it will increase. The opponents defend the traditional view concerning the holiness of life, which fully eliminates the right to death, and the more so the doctors' (or other persons') right to kill a patient intentionally for the sake of mercy. The position of religious ethics on the whole remains negative. An opinion prevails that only God disposes of human life and death, and human suffering has special meaning from the theological point of view. E. Kant was categorically against euthanasia proceeding from his ethical positions of respect toward personality.

If a patient suffers an incurable illness and is in a hopeless state, a doctor's primary duty is to alleviate his/her suffering and to console the patient. The following important circumstances, which relate to the ethical discussions on the acceptability of active euthanasia, should be taken into account:

1) enormous success of medicine in its struggle against pain, which is the main reason of the seriously ill patients suffering;

2) gradual transition of many illnesses from the class of incurable to the class of curable illness or ones with protracted remissions with the progress of medicine;

3) quickly changing emotional state in a great number of patients — from despair with a desire to end their life, to stormy delight at any glimmer of hope.

On the whole, the question of ethical permissibility of euthanasia is far from being solved because of the absence of an acceptable biosocial definition of life. The main question has the following aspects: what is a human life? Does it have the highest value, or the absence of suffering is more valuable? If we give a purely biological answer to the question concerning life (such as "life is a form of existence of protein bodies"), social and moral problems will remain unsolved; if we choose a purely sociological answer ("human life is activity for the good of the society"), the biological and moral problems will not be solved.

If we understand death in the traditional way as cessation of all the functions of the human organism (breathing, heartbeat, etc.), it is hard to find ethical justification for euthanasia. If we understand death as delivery from unnecessary and senseless suffering caused by the irreversible processes of dying, euthanasia will appear not as a morally forbidden choice between life and death but only as a choice between dying and death (painful and prolonged dying versus easy and rapid death). If the human death will be defined in connection with the death of one but the most important for a human being organ — the brain — numerous groups of seriously ill and dying patients will become the proper contingent for euthanasia. This last criterion of death — the brain death — acquires all the greater number of supporters, especially among doctors and medical personnel, because they have several weighty enough theoretical and (especially) pragmatic arguments in its favour. The problem of defining death and the morality of euthanasia is closely associated with another, no less important and dramatic problem — transplantation of organs. The mainline development of medicine took the way of all the more successful technologies of human organs transplantation from donors to recipients. For this reason the need in donors, including embryos, will increase with time.

In 1987 the World Medical Assembly (Madrid, Spain) adopted the "Declaration on Euthanasia" (Supplement 8), which stated that "Euthanasia, that is the act of deliberately ending the life of a patient, even at the patient's own request or at the request of close relatives, is unethical. This does not prevent the physician from respecting the desire of a patient to allow the natural process of death to follow its course in the terminal phase of sickness."*

The problem of euthanasia from the ethical point of view has the closest connection with the major duty-oriented principle — the principle of "abstaining from killing". This principle can conflict with the ethical principles oriented at the consequences — the principles of beneficence, non-malfeasance, respect for autonomy, veracity and fidelity.

The basic ethical conflict consists in working out the tactics of managing a patient who is in a critical or terminal state, but is still alive in accordance

* http://www.wma.net/e/policy/e13.htm

with the legal definition of death. This situation requires an ethical distinction between the categories of "killing" and "letting die"; between withholding the life supporting treatment and its stopping; between the ordinary and unusual variants of treatment; between the direct and indirect termination of life (fig.5).

The distinctions between the categories of "killing" (active euthanasia) and "letting die" (passive euthanasia) are generally accepted in the whole world. If a doctor considers that it would be better to die for a terminally sick patient and (for the sake of "mercy") gives him a mortal dose of medicine, this action is an example (paradigm) of euthanasia. On the other hand, if a doctor *lets the patient die* (by disconnecting him/her from the artificial ventilation apparatus), it should not be considered as euthanasia (if we do not understand it in a wide sense). Moral distinctions between these approaches are clearly understood at the intuitional level. In addition, active killing is illegal, while letting die is legal. And, finally, a doctor's participation in active killing will change his role and harm his moral status. The importance of distinctions between granting the patient "death for the sake of mercy" and "letting him die" is grounded by the arguments of respect for autonomy, the analysis of different consequences, and the reasons of the non-malfeasance principle.

In the ethics of managing a dying patient it is important to differentiate between stopping the life-supporting therapy and withholding it. Some variants of life-supporting treatment are invasive and physically burdensome

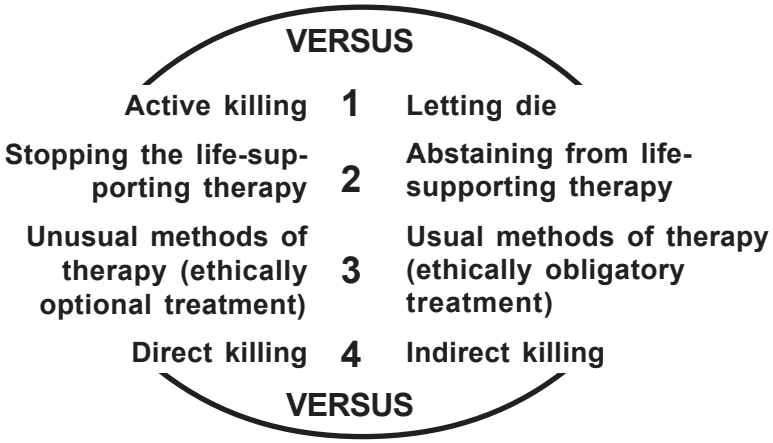

Fig 5. Ethical dilemmas of managing a patient in a critical or terminal state

for a patient, so the patient's choice is not only a choice between life and death. If a patient is dying from cancer, he decides whether to subject himself to chemotherapy, which can prolong his life for a few months, but on the other hand cause other sufferings, for example, nausea and weakness. Similarly, if a patient is dying at an inpatient department, he can make a choice whether to go home and die in a "natural" way or continue the treatment, which will prolong his life for a few days or weeks. In both cases the patient is forced to compare the "value" of prolonging his life and the possible suffering, related to this prolongation.

The withholding life-supporting therapy or stopping it does not conflict with the principle of non-malfeasance, in obedience to which a doctor is obliged to provide the patient with *grounded, rational* treatment and to avoid those variants of treatment, which are "harmful" or undesirable for the patient. When a doctor stops rendering medical help at the patient's will, he still fulfils the commitment to provide *grounded rational* treatment. The obligation to provide treatment does not imply the obligation to "force" the treatment on a patient, who does not want it. Besides, the doctor does not provide *harmful* treatment. The cessation of treatment is not a variant of medical care but rather withholding its further rendering.

There is another point of view at the stopping of treatment: if a doctor has a serious moral bias against this approach, he can transfer the patient to the care of another doctor, who will be able to carry out the patient's will. Indeed, a doctor is not obliged to carry out actions which conflict with his moral values. Nevertheless, if a doctor continues to conduct the "undesired" treatment against a patient's will, it violates the patient's right to autonomy, even if it lasts for a short time till the patient is transferred to another doctor's care.

Some opponents of the stopping of life-supporting treatment consider that providing the patient with food and liquid is ethically obligatory as a symbolic display of care and compassion. In their opinion, the abstaining from providing the patient with liquid and food is the same as forcing him to starve and thirst to death. Nevertheless, it is far from obvious that providing the patient with nutrients through a naso-gastric pipe (often against his will) can be compared to a normal method of appeasing his/her hunger.

There is no principle ethical difference between the concepts of withholding life-supporting treatment and stopping to provide it. The cessation of treatment appears emotionally more difficult than withholding it, because a doctor carries out an *action* which accelerates the onset of death. On the other hand, when he abstains from treatment, death is rather a result of his *inactivity*. However, presently the majority of specialists in the field of bioethics do not emphasize the distinctions between these two actions.

In any case, a doctor must be sure that the patient is capable of making decisions concerning the state of his/her health, before executing such decisions. In particular, the doctor must understand that in his decision-making the patient can be influenced by not understanding the prognosis of his disease, or by a possible state of depression. It is undoubtedly necessary to try to provide maximal comfort and dignity for the patients who require life-supporting treatment, and they must receive this treatment. If all this is granted, there is a lower probability of a situation, in which a patient makes a decision to stop the treatment because he experiences suffering or expects to suffer in future.

The problem of withholding (or stopping) resuscitation help (the do-not-resuscitate orders) is a topical issue in the bioethics of critical conditions. It is rightful to consider this question in the following occasions: in the case of direct requirement of a patient or his/her family; a patient's senility; grave prognosis; severe brain damage; an extreme degree of suffering in a chronically or terminally sick patient; unjustified high expenses of treatment and medical care as compared to the low probability of the patient's recovery. It is also possible to select three basic groups of reasons giving a right to refuse the resuscitation help to the patient: 1) the cardiopulmonary resuscitation will surely be vain and will bring no benefit to the patient; 2) the quality of life after the cardiopulmonary resuscitation will be unacceptable for the patient; 3) the patient's quality of life is unacceptable even before the beginning of cardiopulmonary resuscitation.

While examining the first group of reasons, we should point out that according to a generally recognised ethical principle a doctor has no obligations to provide, and a patient or his family do not have a right to demand for such a type of medical treatment, which does not result in provable benefit. A patient or his relatives can suppose by mistake that this vain treatment will bring a benefit, but this supposed benefit does not give them a right to insist on such treatment. The following situation can serve as an illustration of the second group of reasons. A patient had experienced the stop of his heart activity before and was resuscitated, at present he is disabled, but he and his family have adjusted to this quality of life. Nevertheless, if the patient's heart stops again and the repeated cardiopulmonary resuscitation will be carried out successfully, the subsequent quality of his life will surely worsen and will become unacceptable for the patient. Finally, the third group of reasons includes the situations when before the development of a critical condition (for instance, stop of the heart activity with subsequent resuscitation) the quality of the patient's life is unacceptable for him and/or for his family members. Such situations can take place in extremely serious chronic or terminal patients.

These examples are indicative of a certain vagueness in the modern interpretation of the purposes of applying the resuscitation measures. The

principle developed by the National Council of Cardiopulmonary Resuscitation and Emergency Cardiologic Help (the USA) states: "The purpose of the cardiopulmonary resuscitation consists in the prevention of sudden unexpected death. The cardiopulmonary resuscitation is not indicated in certain situations, for example in the cases of terminal irreversible disease, when death is not unexpected". It is obvious that the cases of terminal irreversible diseases can involve all the three above-stated groups of reasons, which allow to give up resuscitation. On the other hand, there is a probability of such cases of terminal irreversible disease, when the withholding the resuscitation measures can not be justified, because the patient accepts the quality of life he had before and will have after these measures are taken.

It is possible to differentiate some variants of stopping the life-supporting treatment, selecting "usual" and "unusual" methods of therapy, which accordingly are "ethically obligatory" and "ethically optional" kinds of treatment. In obedience to this conception, "usual" treatment must be conducted, while "unusual" treatment can be stopped. A number of criteria were offered for the differentiation of these variants of treatment. These criteria imply usualness (traditionalism), naturalness, complexity, cost, invasiveness, and most important, correlation between the probable benefit and the painfulness for the patient.

The main grounds for decision-making concerning carrying out or stopping the life-supporting treatment and using its variants is the question of its expedience for the patient. Consequently, the variants of treatment are not always objectively "usual" or "unusual". For example, artificial nutrition and providing with liquid is often considered to be a "usual", normal variant of therapy, which should not be stopped at any circumstances. Nevertheless, such treatment is often very painful or uncomfortable for a patient, resulting in his protracted immobilization, and it is contingent with certain risks (for example, the surgical risk in gastrostomy, or the risk of aspiration pneumonia development if a nasogastric probe is used).

In the ethical estimation of a terminal patient management it is necessary to distinguish direct and indirect killing from the positions of the so-called double effect doctrine. The main idea is that in certain situations an action can cause two effects: one of them is wished for (desirable), and the other is not wished for (undesirable). The doctrine of double effect asserts that an undesirable effect is morally acceptable, if the action is not amoral in itself, and its undesirable consequences are not related to the desirable effect. For example, the death of anaesthesia during a complicated operation is morally permissible according to the doctrine of double effect, because the desirable result was the patient's recovery after the operation. Another example: the prescription of a high dose of drugs to alleviate intensive pain

in a patient who is in a critical state entails the risk of oppressing the breathing and even death. However, such a death can also be morally justified in accordance with the doctrine of double effect, because it was not the purpose planned by the doctor, although it could be foreseen. On the other hand, if it is possible to use analgesics so that the risk of death would be minimised, surely, they must be used in this way. At present physicians have a great number of different remedies which enable them either to liquidate the pain in a mortally sick person or to decrease it considerably, making it bearable. However, the use of such remedies is frequently limited by the fear, that a patient can get addicted to analgesics. In this connection the 42nd World Medical Assembly (1990, California, USA) adopted the Statement on the Care of Patients with Severe Chronic Pain in Terminal Illness*. The preface to this document says: "The care of terminally ill patients with severe chronic pain should provide treatment that permits these patients to close their lives with dignity and purpose. Analgesics, both opioid and nonopioid, are available and when properly used, can provide effective relief of pain for most terminally ill patients. It is incumbent on the physician and on all others who care for the dying patient with severe chronic pain to understand clearly the dynamics of the pain experience, the clinical pharmacology of analgesics, and the needs of the patient, family and friends. It also is imperative that governments assure that medically necessary quantities of opioid analgesics are available for appropriate application in the management of severe chronic pain."

A patient's right to "autonomy" (making independent decisions) implies, that a doctor should have respectful and responsible attitude to a patient's decision as to the refusal or discontinuation of the medical care provided to him. This principle also concerns the cases, when the withholding or stopping the medical care can result in the patient's death. This right for patients is recognised by the majority of specialists in bioethics.

Incompetent patients who were competent before could have expressed orally (or in the written form) their will in relation to their medical treatment. Therefore it is very important to investigate such circumstances with the purpose of observing the principle of the patient's autonomy and to make a substitute decision, taking into account the existing documents and the evidence of the patient's relatives and friends.

In regard to a patient who has never been competent and, besides, does not have a family, the substitute decision can not be made on the basis of respect for autonomy, proceeding from the definition of this principle. In these cases it is necessary to use another principle — the principle of maximal individual benefit for the patient's well-being (after Hippocrates). How-

* Adopted by the 42nd World Medical Assembly Rancho Mirage, CA., USA, October 1990, http://www.wma.net/e/policy/c2.htm

ever, in these cases there is an exceptionally difficult problem: do incompetent patients have the "best interests"? Even if the answer to this question is positive, can the theory of ethical values specify, what are these interests? Medical interests do not determine all the content of a person's well-being. Can the principle of social benefit or justice help in determining the patient's best interests? It is quite clear, that there are no legal or moral grounds for a doctor to make a decision to stop or withhold the life-supporting therapy. Who in this case can make a substitute decision in regard to this especially ethically vulnerable group of patients? Should specially appointed officials do it?

Some of these questions can be answered on the basis of the World Medical Association Declaration on Terminal Illness adopted by the 35th World Medical Assembly (Venice, Italy, 1983) *. (Supplement 9).

As it was mentioned above, in the last few years a significant number patients whose physiological state is diagnosed as intermediate between life and death are concentrated at the hospitals of many economically developed countries in the world, especially the USA. These patients suffer from different incurable diseases, including the late stages of cancer or multiple sclerosis. A few decades ago such patients were doomed to rapid death. Owing to the modern medical technologies their life can be preserved for many years. The case of C. Quinlan (USA) was a kind of record of such artificially supported longevity. At the age of 21 in 1975 she became a victim of a motor-car accident, lapsed into a comatose state and stayed in it for ten years. After a judicial trial which defined her state as irreversible, the decision to disconnect her from the life-supporting apparatus was made. But even before that the analysis of numerous similar cases resulted in the revision of the traditional definition: it was decided to proceed not from the state of the respiratory system and heartbeat, but from the estimation of the state of brain, the main organ of human organism, as the criterion of the patient's state. Thus, in the early 1980s a new criterion was first offered: "the brain death".

We can foresee that similar situations will become more common and last for a still longer time. Even if we do not refer to the financial aspect of the problem (this kind of medical service is very expensive, and the resources are often needed to render the first aid to other patients), such situations involve quite a number of purely moral problems. Is this patient a human being in the complete sense of this word, is he/she a moral subject and a member of society? Shouldn't we use here a special term — "vegetable existence" — and determine its meaning? The problem becomes especially difficult when the question arises as to how to put an end to such existence and who must undertake the mission of doing this. Neither a

* http://www.wma.net/e/policy/handbook.htm

doctor, nor the medical personnel, following the Hippocratic Oath and its main principle of non-malfeasance, as well as the principle prohibition of killing, are not inclined to carry out these procedures, as they concern a living human being. But is this person alive, and what is "a living human being" and, in a wider sense, what is a "living creature" ? There is no clarity in this question. It is still more impossible from the ethical point of view to entrust the execution of the procedure of disconnecting the patient from the apparatus to the patient's relatives. And in the cases when a patient experiences intensive physical suffering and pain the applied resuscitation apparatus only prolongs the patient's suffering.

A patient in the "chronic vegetative state" is usually considered to be alive only in the biological sense. However, if we consider such people as really dead, serious questions arise. For example, how severe the damage of the brain cortex should be in order to register death? When does a human being who had permanently lost his/her consciousness stop being a personality, what an attitude should we take towards him/her? Are we obliged to treat him/her as a person, continuing to take all measures to maintain his/her life? Or is it expedient to limit the care of him and "let him die" ? In the opinion of Ch. Culver and B. Gert, an organism which has stopped being a personality should not "require" treatment as a personality. This means that there is no need to undertake persistent permanent efforts to support life in such patients, because such efforts are not justified either from the economic or from the humanitarian point of view. On the other hand, it is impermissible to force somebody to deprive such a patient of life actively. In spite of the fact that the organism is not a person any more, it still looks like one. An acceptable way out of this situation is to stop taking care of the patient, including both the medical provision and the routine care, and thus "let the patient die". It is most important, that such a patient does not experience suffering from the lack of help, because he is not a personality any more after he has lost his consciousness irreversibly. Every patient who has at least a minimal ability to react to pain or feel some discomfort is considered to be a personality.

An important theoretical and practical contribution to the ethical analysis of this problem was made by the "Statement on Persistent Vegetative State" adopted by the 41st World Medical Assembly (Hong Kong, 1989) (Supplement 10).

The problems of withholding or stopping the therapy of a critically sick patient have certain specific features in the paediatric practice. One of the debatable and not finally solved questions of the modern medicine is the question concerning the grounds on which the "usual" medical treatment can be stopped in a certain category of new-born infants. This category includes children with serious diseases and developmental anomalies of the

central nervous system. Before the modern achievements of surgery and paediatrics were implemented these infants died of "natural" causes. Today many of them live for long time, although in a great number of cases have serious defects of mental development, are very limited in regard to socializing with others and the realization of all the potential of human development. Considering such serious deficiencies, the doctors often discuss the issue of withholding the treatment of this category if new-born infants with their parents.

If we agree to the fact, that new-born children with grave vices of the central nervous system are, nevertheless, persons, there still remains a topical question concerning the circumstances, in which the expected outcome of treatment is so undesirable, that the withholding providing the medical care is justified. In the opinion of many parents of such children, their sufferings and limited quality of life make the social and economic expenses on their treatment unjustified. The most serious reason for the withholding the treatment of such children consists in the fact that the medical help can contradict to the *child's* interests, irrespective of the influence of its outcome on other people. Grave innate developmental anomalies in children result in the state, when they become a "burden to themselves". One of the factors which cause suffering in these patients is intensive permanent physical pain and repeated surgery. Such children can experience repeated fractures and dislocations. The dysfunction of the shunt in hydrocephaly results in the need for several operations. Mental and social imperfectness is an important unfavourable factor. Many of these children will be never able to walk, even with the help of prosthetic appliances, will never learn to socialize with their peers normally, will never develop any working skills and only in rare cases will be apt in self-service. In the cases of profound mental retardation they will exist in a "vegetative state" in their beds. Parents often give up such children and they are forced to spend the greater part of their lives at hospitals, "contesting" with a number of medical problems. Can we assert with certainty, that such life is worth living?

On the other hand, a child's low quality of life and his/her inability to learn and form social relations can be conditioned not only by innate defects, but also by other people's inappropriate social position in relation to him/her. Psychosocial suffering can be caused by the fact, that healthy normal people refuse to communicate with a mentally retarded child. In certain conditions and with some efforts it is possible to help such children adjust to their social environment, and when they do, it becomes improper to say that death for them would be better than life. Unfortunately, some children are disabled so gravely, that their response to love, care and education, in other words — their ability to develop as a personality, is absolutely minimal.

In addition to the arguments related to the quality of life of the mentally retarded children, the supporters of their death justification advance arguments concerning the psychological, social and economic expenses of family and society for the maintenance of such children. The well-known child neurosurgeon Matson considers that: "the doctors and society are responsible for providing the patients with medical care and minimizing their suffering; but at the same time, they must not unnecessarily prolong the personal, domestic and public sufferings related to the patient; they should not conduct multiple manipulations or carry out expensive, protracted stationary treatment of the children, whose chances for acceptable growth and development are too low".

As a rule, the birth of a child with grave innate defects is a serious blow for a family. During a very short time the parents begin to feel grief from the loss of the "normal, expected" child, anger at their fate, the sense of doom, disgust, helplessness and disbelief. Many of them feel either personal guilt, or blame the spouse for what has happened. They are afraid, that their social position can change for a long period of time. A question arises, how does the child's treatment influence the psychical and other reactions of his/her family members, as compared to the situation when the child is not treated. If a child is treated at an inpatient department and after that returns home, the parents encounter a number of problems. They have to learn to take care of such a disabled child, they can have financial and psychological difficulties and experience contradictory feelings. The mother has to cope with much more hardships as compared to a mother of a healthy child, especially in the situation of frequent hospitalizations. The family plans in regard to the birth of a next child can also change. The feelings of grief and guilt which the parents experience after the child's birth can become "chronic". The development of such a frustrating situation does not imply the need in withholding the child's treatment or his/her transmission to a special institution. Individual or group psychological training or counselling can alleviate the suffering of the family and help the parents to coupe with increasing psychological conflicts.

The medical personnel also experiences a certain measure of discomfort (it certainly can not be compared to the parents') when an infant with congenital pathology is born. The doctor has to solve the problem of explaining the nature of the child's defect and the reasons of its development to the parents, and to a certain extent shares their emotional shock. Often the doctor (obstetrician) feels guilt for failing to do everything possible for the birth of a normal child. Besides, the parents can feel certain anger and mistrust in the doctor's competence. A doctor can also feel that his professional skills and experience are used incorrectly, when they are directed at the purpose of sustaining the life of a child who has no perspectives.

The prolongation of the life of children with grave congenital defects causes a number of social problems. Medical resources which could be used for the treatment of children with a more favourable prognosis, are used for expensive surgical treatment and resuscitation support of the children, who's life can be prolonged only for a few months or years.

Probably the decision on limiting or stopping the treatment should be made in the process of joint discussion of the situation by the parents and doctors with the participation (if necessary) of the members of an ethical committee, which are organized at large clinics, with the consideration of legal norms, ethnic, cultural, social and religious views. Every medical institution can and must develop its bioethical principles of managing the children (new-born infants) with serious defects. The treatment can be limited or stopped in the cases, when irrespective of its provision the child's death appears inevitable, or there is a high risk of grave physical or mental disability. It is expedient to realize this approach also in the cases, when the survival with moderate disability is possible, but it is quite certain that the child will experience chronic pain, suffering, repeated hospitalizations and invasive procedures in future, and will die in childhood. It is necessary, that if the decision is made to stop the medicinal treatment and sustentation by technical means, the child would still be provided with food and liquid.

During the last years the public attention was focused on the cases of suicide with the assistance of a doctor. Such suicide is legalized in the Netherlands and in Oregon (USA). The World Medical Assembly (1992) adopted the "Statement on Physician-Assisted Suicide"*, in which it gave a negative ethical estimation of this practice.

Usually the objects of this variant of suicide are patients with incurable or mortal diseases, who experience intensive pain and suffering, are aware of the results of their actions and have made an independent decision on committing suicide. The patients who intend to end their life by suicide frequently are in the state of depression, which often accompanies mortal diseases.

Pros and cons of the physician-assisted suicide are similar to the reasons presented by the supporters and opponents of voluntarily active euthanasia. The physician-assisted suicide involves the doctor in the performance of one or both following "objectives" 1) to provide the patient with information on accomplishing the suicide "effectively"; 2) to provide the means, necessary for the commitment of an "effective" suicide (in the majority of cases by writing a recipe for a mortal dose of medicine). Other ways of a doctor's participation in the realization of suicide can include moral support of the patient's decision, "supervision" over the realization of suicide, and

* 44th World Medical Assembly, Marbella, Spain, September 1992, http://www.wma.net/e/policy/p13.htm

rendering help to the patient in making the necessary physical actions (for example, extremely weak patients may need help in taking the lethal dose of medicine). There were cases when patients used appliances constructed by doctors, who instructed the patients how to use them with the purpose of suicide. Both in active euthanasia and in physician-assisted suicide, the doctor plays an active part in the patient's death. However, there is a difference between these two acts — in active euthanasia it is the doctor who kills the patient, while in the case of physician-assisted suicide it is the patient who kills himself.

The prevailing ethical estimation of both active euthanasia and physician-assisted suicide consists in considering these actions amoral and subject to condemnation on the part of medical professionals. At the session of the Supreme Court of USA in 1997 the constitutional correctness of the prohibition of physician-assisted suicide was unanimously supported. At the same time, a patient's right to waiver the medical care (which, in principle, can be also considered as a variant of suicide) is morally acceptable and proceeds from the principle of respect for autonomy (as it was mentioned above).

Section VI
MEDICAL-ETHICS AND LEGAL ISSUES OF HUMAN REPRODUCTION

"So God created man in his own image, in the image of God he created him; male and female he created them. God blessed them and said to them: "Be fruitful and increase in number; fill the earth and subdue it."

Genesis 1, 27, 28

MEDICAL-ETHICS ESTIMATION OF ARTIFICIAL ABORTION

In the society and medicine there always existed and still exists a number of bioethical problems in connection with the procreation (from the Lat. *procreacio* — birth, reproduction of posterity) or reproduction of people. Moral and ethical, social and legal problems arise both in connection with undesirable pregnancy and in connection with the inability to conceive or bear a child. The creation of new reproduction technologies generate new problems in bioethics.

The artificial termination of pregnancy is more widespread in our days than at any time in the previous history. Daily about 100 million sexual intercourses are accomplished in the world, conception occurs in 910 000 cases, and in 10% of these cases pregnancy ends with artificial abortion. The concern is caused both by the medical consequences of abortions (maternal morbidity which often results in sterility or death) and morally-legal problems of its permissibility at the different terms of pregnancy and its legislative regulation.

In the most wide context the medical ethics estimation of the artificial abortion is based on the analysis of the reasons of this medical manipulation in relation to the discussion of basic laws of the human foetus biological development. The essence of this ethical problem consists in the determi-

nation of the period of foetation (if such can be named) and for what reason (if such can be formulated) the abortion can be considered ethically acceptable.

The potential reasons for abortion are:

1. Threat to the mother's life in the case of continuing pregnancy;
2. Threat to the mother's physical and/or mental health if the pregnancy is not terminated;
3. High probability or confidence that the pregnancy will end with the birth of an infant with a serious disease;
4. Pregnancy which was a result of a rape or incest;
5. Pregnancy of an unmarried woman, when the birth of a child would cause social stigmatisation or violation of traditions, norms, or laws;
6. Various individual situations in which the birth of a child would exert negative influence on the wellbeing of the mother, the married couple or all the family, including the already born children.

The last category, presumably, is the most widespread one, when a woman is oriented at her professional career, when the birth of a child, in the opinion of the married couple, can violate the harmony of their relations or will result in the excessive financial expenses, etc.

Two radical approaches exist to the ethical estimation of the permissibility of abortion: *conservative* and *liberal*. The conservative point of view consists in the assertion that abortion can never be ethically justified or that abortion is permissible only to rescue the pregnant woman's life. The liberal point of view consists in the ethical acceptability of abortion in all cases, i.e. at any period of pregnancy and regardless of its reason. The supporters of the third — *centrist* — position suppose that abortion is morally acceptable up to a certain stage of biological foetation and/or assert that some reasons create sufficient ethical grounds for abortion, while others do not.

In the discussions concerning the ethical acceptability of abortion the major question consists in the determination of *the moral status of the foetus*. To say that a foetus possesses the complete moral status means to say that it is an object of all moral judgements to the same extent as a fully formed individual. In particular, the recognition of the complete moral status of a foetus practically means that a foetus has a right to life, which should be considered as seriously as the right to life of any other human being. On the other hand, to say that a foetus does not possess a (substantial) moral status, means to say that it has no rights which would be worth of discussion. In particular such approach denies a substantial right to life. Conservatives usually assert that a foetus possesses all the plenitude of moral status, whereas the liberals insist that a foetus does not have a substantial moral status, and some centrists consider that it has a partial moral status.

The discussions of the moral status often include the laws of ontogenesis and are related to the question concerning the moment of foetation with which the human life begins. In this context of discussion a human being possesses a complete moral status, while a "non-human being" does not have a meaningful moral status and, consequently, the concept of partial moral status is eliminated. The central problem consists in the need to define distinctions between a human being and a "non-human being", to make clear distinctions between them and to attain a consent in the methodology of these actions. Conservatives, as a rule, consider that the demarcation line should be drawn from the moment of conception as an exceptionally indisputable starting point. They disagree with the attempts of drawing the demarcation line in connection with any other important points of ontogenesis, such as implantation, movement, heartbeat or birth, saying that a foetus develops continuously and it is impossible to find any limits of its ontogenesis. Conservatives are sure that a demarcation line can not go through any period of continuous foetation. It will be constantly moved till it reaches the point of conception, where it is possible to find the objective grounds of the beginning of a human life. As a result of conception a complete genetic code is formed, while it did not exist before the conception.

The liberal point of view at the demarcation line consists in the opinion that a foetus can not be considered as human being even at the latest stages of its development. This, certainly, does not mean that the biological belonging of a foetus to the human species is called in question. Rather, the liberals state, that a foetus is not a human being in the moral understanding, that it does not have a meaningful moral status. The "demarcation line" is usually drawn by the supporters of liberal views at the level of birth (and sometimes even later). From the liberal point of view a foetus does not have a greater right to life, than the cells, tissues and organs which are ablated during some surgical operation. From the conservatives' point of view, the complete moral status of a foetus determines the same moral impermissibility of abortion (with the possible exception for the cases of rescuing the mother's life), as the murder of a human being.

The participants of discussions concerning the ethical aspects of abortion concentrate most intently on the questions which relate to the stages of foetation. The attempts at considering the regularities of the foetus development are methodologically interesting; the formation of its heart, brain and higher brain regions are correlated with the acquisition of the moral status and, consequently, with the grounds for different degree of acceptability of abortion at different periods of gestation. The theoretical basis of this purpose-directed estimation of the stages of foetal development consists in finding common features (analogies) in the *abortion* and the *known definitions of death based on the heart, brain or the higher regions of brain death.*

Conception is the major period of ontogenesis, when a spermatozoon, unites with an ovule and a one-celled zygote, with a complete genetic code of 23 pairs of chromosomes is formed. In the process of division a one-celled zygote turns into a multi-cellular zygote, which moves down the oviduct and is gradually implanted in the uterus wall. Legalistically the term "zygote" is used till the time of complete implantation — during 15 days from the moment of conception. Then to the end of the 11th week of gestation, during the so-called embryonic period, the formation of organs and systems takes place. The period of foetation lasts from the beginning of the 12th week to the moment of birth. We should observe that the term "foetus" is often used in its wide sense to denote an unborn human being, regardless of the stage of its intrauterine development. There are very important moments in the foetation, which take a special place in the discussions on the ethical acceptability of abortion. The forming of the heart is completed by the 8th week of gestation, but the full functional ability of the heart develops later. There is a correlation between the heart-oriented determination of death and the ethically acceptable terms of abortion. There is a point of view that the foetus acquires a moral status at the time of the structurally-functional forming of its heart. In Ukraine, as is generally known, abortion "on request" is made in the term of no more than 12 weeks of pregnancy.

Usually in the term of gestation which corresponds to the 18th–20th weeks of pregnancy, the woman begins to feel the motions of the foetus, which are designated as foetus movements. In the same term of gestation the foetal heartbeat begins to be heard through the abdominal wall. The specialists in ethics, which suppose that a foetus acquires complete moral status from the moment of neurological integration ability development, consider abortion to be acceptable up to this stage. Such approach is symmetric with the determination of death on the basis of the total brain death.

Approximately by the 22nd–24th weeks of gestation the foetus becomes viable. The higher brain is formed by this period. The supporters of the point of view, according to which a foetus acquires the moral status from this time, consider the abortion later than this term ethically unacceptable. There is a symmetry of this approach with the determination of death on the basis of the higher brain death.

The Orthodoxy and Catholic Churches, Islam Judaism and other religions support the conservative views concerning the unacceptability of abortion. They are convinced opponents of the artificial termination of pregnancy. According to the Christian dogma the moment of conception is the moment of the human soul origin. Therefore the conscious elimination of an embryo, wherever it takes place — in the maternal womb or out of it — is a sin of murder. The Orthodoxy Church considers the intentional termi-

nation of pregnancy (abortion) a grave sin. Canonical rules equate abortion with murder. This estimation is based on the belief that the origin of a human being is a Divine gift, therefore from the moment of conception every trenching upon the life of a future human being is a crime. The Church considers the wide prevalence and justification of abortions in the modern society as a threat to the future of the humanity and an obvious sign of moral degradation. The loyalty to the biblical view concerning the holiness and pricelessness of a human life from its very beginning is incompatible with the recognition of the "freedom of choice" of a woman in disposing of the fate of her foetus. Besides, an abortion is a serious threat to a woman's physical and mental health. The Church also considers that its duty consists in defending the most vulnerable and dependent human creatures, such as unborn children.

The Catholic Church protects the dignity and life of every person, regardless of the stage of development, the state of health and consciousness he/she is in. Pope Paul the VI wrote in his encyclicals "Humanae Vitae": "We must officially declare once again: the direct termination of the beginning process of foetation in the mother's organism, foremost a direct abortion — even if it is carried out with medical aims — is an impermissible method of limitation of the number of children, and it should be absolutely rejected". Pope John Paul the II specified in his encyclicals "Evangelium Vitae" that "abortion is always a grave moral misconduct, because it is an intentional murder of an innocent human being". The doctor of medicine, monsignor J. Sudo, considers that the inseparable unity of human spirit and body makes us admit that the beginning of a human corporal sphere means the beginning of the very human personality.

The Islamise theologians consider that Prophet Muhammad, speaking about the basic stages of the embryonic development in the maternal womb, mentioned that after the expiration of 120 days of foetation Lord sends an angel which breathes a soul into a forming baby. On the basis of this the Islamise theologians consider the abortion permissible up to this term in the cases of absolute necessity.

In the opinion of Judaists the soul is infused in the embryo on the 40th day after conception. Before this the embryo is no more than simply a cell or a conglomerate of cells. Nevertheless, Judaists considers that abortion is an intentional murder.

The most liberal view at abortions was expressed by the leaders of the feminist movement. In 1916 Margaret Sanger * founded the Birth Control League. Being a well-known leader of the feminist movement in America, she asserted: "Birth control is no more than eliminating the human weeds

* Sanger, Margaret Higgins, 1883–1966, American leader in the birth control movement, b. Corning, N.Y.

by preventing the birth of defective people or those who can become defective." M. Sanger attributed to the "defective" not only the mentally retarded, but also the non-white and even the simply poor population. In 1952 M. Sanger founded the International Planned Parenthood Federation (IPPF), which co-ordinated the activity of national organizations on birth control. In the opinion of IPPF, a woman has a right to free responsible choice whether to bear her conceived foetus or to abort it.

One of the first activists of the movement for the women's right to abortion A. Davis said: "Whatever rights the women get — to vote at the elections, get education, etc. — all this has no value, if we do not have a right to dispose of our own body and to control events which happen to us, if men, from whom we can become pregnant by virtue of chance, deception or force, can change our fate." The experts of IPPF point out: "The way of the development of all the European countries must go not through the limitation of the reproduction choice, but rather through its expansion." The IPPF ideologists talk about the "double strategy": in the modern society a woman must have an access to sexual enlightening, she must have a choice of facilities to regulate her fecundity. However, in the presence of all these possibilities she must also have access to safe and legal abortion.

The conservative and liberal positions are two poles in the spectrum of ethical views concerning the abortion. The centrist point of view at the abortion, unlike the polar opinions, can not be reduced neither to intensive condemnation nor to non-compromise defence of the medical abortion practice. Centrists consider that some abortions are morally justified, and some are morally unacceptable. In some centrists views the stage of foetation is an important factor in the moral analysis. In others — the consideration of reasons for which the abortion is made has substantial importance.

Usually the centrist analysis of the ethical acceptability of abortion suggests to take into account both the stage and reasons of terminating pregnancy. The practice of terminating pregnancy is a component part of *social policy*. The ethical estimation of abortion is carried out both by the adherents of the "right to life" party, and the supporters of the "right to choice" party. The method of abortion is sometimes mentioned in the discussions. In the first trimester of pregnancy abortion is made by the following methods: 1) scraping of the internal wall of the uterus cavity after the dilation of the cervix; 2) vacuum aspiration; 3) manual vacuum aspiration under the control of ultrasonography. The theory and practice of terminating pregnancy at its early stages with chemical substances received ambiguous ethical estimation. For instance, the development of the substance RU 486 (mifepristone) as the "abortive drug" in France became a reason of serious ethical debates. The use of methotrexate with the purpose of suppressing the foetal cells division became another important method of chemical ter-

mination of early pregnancy. The new technology involves the combination of this kind of chemical remedy with preparations which cause the myometrium contraction. The supporters of the liberal approach to abortions consider the use of the chemical method as a legal, private, non-surgical form of abortion, a termination of pregnancy to which every woman has a moral right. The supporters of conservative views are categorically against the legal availability of such chemical preparations. They characterize this method as a "chemical warfare against unborn children" and treat the applied chemical substances as "human pesticides".

The abortion after the first trimester of pregnancy is executed with the following methods: 1) dilatation and evacuation; 2) inductive technologies (injection of salt solution into the amniotic fluid, using prostaglandins); and 3) hysterotomy.

After the development of prenatal diagnostics methods, such as amniocentesis, investigation of the chorionic villi and ultrasonography, a new ethical problem appeared, related to the medical practice, which is applied if genetic or chromosomal pathology in the foetus is discovered. The essence of the problem consists in grounding the ethical acceptability of a selective (genetic) abortion.

The morals and the reproductive risk make an important section of the modern biomedical ethics. There is a point of view, in accordance to which reproduction at the high genetic risk should be considered morally unjustified. At the same time the possibility of selective abortion diminishes the risk of serious genetic diseases.

Another ethical problem related to the reproduction in the conditions of high genetic risk is the question of justification of using forced measures for achieving the social control over individual reproduction decisions. To assert that a certain reproductive choice is amoral is different from saying that forced measures of control over the reproductive choice are morally justified. Such major control measures as sterilization or obligatory amniocentesis with subsequent abortion are rejected in most ethical discussions as actions which violate the fundamental human rights. Obligatory screening programs aimed at the authentication of genetic pathology transmitters are less invasive than other forced measures, but they also get ambiguous estimation of specialists in the field of biomedical ethics.

Abortion belongs to the number of the oldest legal problems. The attitude toward it in the ancient world was ambiguous. Although the Hippocratic Oath mentioned the prohibition of terminating pregnancy ("…I will not give to a woman an abortive remedy"), but at the same time Aristotle considered abortion to be a possible method of birth control, permissible until "sensitivity" and "movement activity" developed in the embryo. In the Ancient Rome abortion was widely practiced; the legal status of an embryo

was interpreted as a part of the mother's body (*pars viscerum*), therefore a woman was not exposed to punishment for killing her foetus or disgorging it from her womb. However, when the Roman empire began to need new soldiers to conquer other lands and an increasing number of slaves, the embryo (*nasciturus* — "expected to be born") acquired some civil rights, and an artificial abortion began to be interpreted as a crime.

The origin of Christianity resulted in the awareness of the value of an embryo. In the epoch of early Christianity abortion was equated to a murder of a human being. According to the Christian view, extermination of a foetus deprives it of the blessing of future christening and is a grave sin.

In the Middle Ages almost in all European countries the implementation of abortion entailed criminal proceeding of both doctor and woman and was punished with the death penalty, imprisonment or penal servitudes. In the XIX century abortions were legislatively forbidden in the USA in all cases, except for those when the situation involved the rescue of a woman's life. The ethical problem of implementation of abortion on medical indication became more topical in the course of society and medicine development.

In the Russian empire of the XIX century the law differentiated the permitted artificial abortion made by a doctor to rescue a woman's life, and an abortion made by a woman or some other person with the criminal purpose of terminating pregnancy. If the person who made a criminal abortion was a member of the medical profession (including midwifes), this was considered an aggravating circumstance.

Soviet Russia was the first state which legalized the "abortion on request" in 1920, but in 1924 the bodies of health protection organised "abortion committees" which gave permission for free abortion, applying class approach. In 1936 a Declaration forbidding abortions was adopted in USSR. This change in policy was connected both with the demographic factor (the decline of population) and with ideology. The permission of abortions seamed to conflict with the claims of official propaganda concerning the permanent growth of the workers' welfare. The growth of the number of criminal abortions in the post-war period caused the change of policy in regard to abortions. In 1955 in USSR the Edict "On the abolition of the prohibition of abortions" was adopted. This document legalized "abortions on request", which had to be made only by persons with special medical education, only before the 12 weeks term of pregnancy, and only at hospitals. As alternative to abortion methods of birth control did not get a wide distribution in the USSR, the number of artificial abortions grew steadily in 1960s to 1980s. In 1987 the Ministry of Health of USSR published the order N 1342 concerning the termination of pregnancy "on social indications". This document permitted to terminate pregnancy at its later terms — at the

woman's will — if such circumstances as divorce during pregnancy or a large family (more than 5 children) were documentarily confirmed. Thus, the legislation on abortion became more and more liberal.

Legislation of different countries has different attitude toward abortion. In the European countries there are four types of laws concerning abortion.

1. Liberal laws permit "abortion on request" (in a small group of countries).

2. Free enough laws permit abortion on numerous medical and social indications (England, Hungary, Iceland, Cyprus, Luxemburg, and Finland).

3. Strict enough laws permit abortion only at some circumstances: threat to a woman's physical or mental health, incurable defects of the foetus, rape and incest (Spain, Portugal, Poland, and Switzerland).

4. Conservative laws either forbid abortions in general, or permit them in exceptional cases, when the pregnancy presents an instant danger for a woman's life (North Ireland, Malta).

From the data of world statistics in 98% of countries abortion is permitted for the sake of rescuing a woman's life, in 62% — to protect her physical and mental health, in 42% — in the cases of pregnancy after rape or incest, in 40% — for the reason of the foetus defects, in 29% — for economic and social reasons, and in 21% — on request.

In the XX century the question of birth control began to be considered in a wider aspect than the question of abortion. This was related to the development of the concepts of "reproductive rights", "reproductive choice", "reproductive health", "contraception", and "family planning".

The reproductive choice is the display of personal moral autonomy in the issues of sexuality and procreation. Above all things the question concerns a person's conscious and responsible attitude toward these issues. Reproductive rights are called to create social pre-conditions for providing reproductive health. They are presented in many international and national legislative documents on human rights. The major of all reproductive rights is the state provided right to have and preserve reproductive health. This right becomes real only on the condition that all modern facilities of family planning are available for women and for men. There is no doubt that abortion is one of the worst methods of family planning, because it is attended by a high risk of complications, the loss of health in general and reproductive health in particular.

In the modern society the conception of family planning is an acknowledged alternative to the practice of widely used abortions. The moral-ethical issues of using modern contraceptives in the general conception of family planning are expounded in the World Medical Assembly "Statement on the Right of a Woman to Contraception", adopted by the 46th World Medical Assembly (Stockholm, Sweden, 1994). Family planning is under-

stood as the idea of "free and responsible parenting," i.e. activity which helps separate persons and matrimonial couples to attain certain reproductive results: to prevent undesirable pregnancy, to give birth to desirable children, to regulate intervals between pregnancies, to control the time of a child birth depending on the parents' age and other factors, to establish the number of children in the family. This concept includes information on the ways of achieving these aims, provision of conscious choice, possibility to use all the spectrum of safe and effective methods. Family planning can include a number of measures, beginning with planning the child birth and the treatment of sterility, and ending with sexual education, consulting on the issues of family life, including the genetic questions.

It should be mentioned that different religious denominations reprobate the artificial methods of birth control. They consider contraception to be a fundamental instrument of sexual amorality, or "sexual liberation". Such contraceptive sexuality rejects God's creative force in His gift of a new human life. The contraceptive sexuality opens a way for approving of any type of sexual conduct, it undermines the chastity of young people.

The best alternative, in the opinion of the Church, is abstention from sex before marriage. The advantages of such conduct include the avoiding of the risk of venereal diseases and HIV infection/AIDS, as well as unexpected pregnancy. In the priests' opinion, accepting children in marriage brings a number of moral and medical advantages. The more children the parents have, the stronger is the family and the smaller is the risk of malignant tumours development in a woman's breast, uterus and ovaries. Nevertheless, natural family planning is acceptable for married couples. The natural methods of family planning are based on watching the physiological signs of fertility (high probability of conception) and infertility (low probability of conception) during the phases of the menstrual cycle. The regulation of the sexual life consists in abstention from sexual acts in the period of ovulation and during a few days after the supposed term of a mature follicle rupture, when the conception is most probable. The calculation of the supposed term of ovulation can be made using a calendar proceeding from the knowledge of the menstrual cycle duration, or on the basis of measuring the basal body temperature, or by investigating the quality of the mucus excreted from the uterus cervix. The natural methods of birth control are not contraceptive or abortive.

The analysis of the modern demographic situation in Ukraine showed that by 2000 the country was in a state of deep demographic crisis, characterized by the diminishing and senescence of the population and shortening of the mean duration of life. This fact dictated the necessity of adopting the National program "Reproductive health 2000" for the period of 2000–2005. The purpose of this program consisted in improving the reproductive health

of the Ukrainian people, as well as the demographic and socio-economic situation in the state. The measures provided by program are directed at further promoting the healthy life style, responsible attitude of the state, society and every citizen toward the reproductive health as an important component of the national health on the whole. The improvement of the normative legal base in force, the optimization of the medical services network and their preventive orientation, the realization of elucidative activity and the organisation of an information campaign directed at the wide strata of population will promote the improvement of the reproductive health of the population, the introduction of modern strategies of family planning and the realization of active demographic policy measures in Ukraine. Today the rate of abortions in Ukraine is one of the highest in the world (in 1996 — 56 per 1000 women of fertile age). According to the data of the sociological questioning "Health-1996", such facilities of contraception as endometrial spirals and condoms were used by 23.9% and 19.9% of women accordingly. The natural method of contraception was used by 19.8% of women, and oral contraceptives —only by 5% of women. Injection implants were used very rarely (0.1% of women). Questioning showed that 11% of women did not want to use any contraceptives at all. 37.1% of the respondents considered that spirals are the most comfortable and reliable contraceptive facilities, 22.3% of respondents prefered condoms, and 15% — the natural method. Only 8% of the questioned women prefered to use oral contraceptives. Almost one third of the male respondents considered that it is best to use no contraceptives at all (29.9%), 21.1% preferred women to use spirals, and 17,9% used condoms.

In Ukraine there is a right to legal safe abortion and responsibility for illegal abortion. In accordance with article 50 of the "Bases of Legislation of Ukraine on Health Protection", the operation of artificial termination of pregnancy (abortion) can be conducted at a woman's will in accredited health institutions in the term of pregnancy not more than 12 weeks. Abortion can be made in some cases in 12 to 28 weeks of pregnancy on social or medical indications in the order established by the Cabinet of Ukraine.

For the implementation of these laws the Ministry of Health issued its order of June, 28, 1994, which approved the Instructions on the order of making the operation of artificial termination of pregnancy in general and on the order of making the abortion at the early terms of pregnancy with the method of vacuum aspiration. The artificial termination of pregnancy can be carried out only at accredited medical institutions and only by a qualified gynaecologist with obligatory anaesthetizing. The artificial termination of pregnancy in minors under 18 years old is carried out at the consent of their parents or other legal representatives. In obedience to the decision of the Cabinet of November, 12, 1993 N 926, the order of artificial

termination of pregnancy at the term from 12 to 28 weeks was established; this document defines the medical (a number of serious infectious, somatic and psychical diseases concomitant with the pregnancy) and social indications (three or more children in the family; divorce during pregnancy; death of the husband during the pregnancy of his wife; pregnancy after rape; imprisonment of the woman or her husband; deprivation of the woman of paternal rights; a disabled child in the family; the husband's serious disease or trauma, which has caused his disability during the pregnancy of his wife) to abortion at these terms of pregnancy. The artificial termination of pregnancy at the terms from 12 to 28 weeks can be carried out in the cases when a woman has other diseases not included in the list, ratified by this governmental decision, if the concomitant continuation of pregnancy and delivery create a risk for the woman's health or life. The artificial termination of pregnancy at the terms from 12 to 28 weeks is carried out with the observance of the propositions of article 43 of the Bases of Legislation of Ukraine on Health Protection concerning the consent of an objectively well-informed and capable patient to the medical interference. The consent of the patient or her legal representative to the interference is not needed in urgent cases, if there is a direct threat to the woman's life.

Presently the process of change of the legislative and regulating base is going on in Ukraine, which will bring it to conformity with the norms and standards of the European Union and WHO, according to which the term of 22 weeks of gestation is considered the borderline of the foetus viability.

The laws of Ukraine provide responsibility for illegal abortions. The abortion made by a doctor is considered illegal in the following cases:

— the existence of medical contra-indications to abortion regardless of the term of pregnancy;

— abortion made outside a special accredited health institution;

— abortion made without proper documentary registration;

— abortion made with forbidden methods;

— at the terms of pregnancy from 12 to 28 weeks, if there are no social or medical indications, in the presence of which artificial termination of pregnancy is allowed at these terms;

— at the terms of pregnancy over 28 weeks, if its termination was not conditioned by a state of absolute necessity.

In addition, punishment is established for abortion made by a person who has no special medical education and for an illegal abortion, which had caused long-term disorder of health or death.

Presently in Ukraine a bill "On Reproductive Rights and Guarantees of Their Realization" is discussed. This Law will consolidate the reproductive rights for the citizens of Ukraine, formulate their contents and provide the guarantees of their realization, proceeding from the priority of human and

citizens' rights and freedoms. The provisions of this Law will provide constitutional human and citizens' rights to the inviolability of private life, personal and family secrets and guarantee the non-interference of the state in the issues of family planning. The Law will establish the duties of the bodies of state power and local government authorities in relation to providing the guarantees for the realization and protection of the physical persons' reproductive health, and will provide a legal basis for the family planning services and free realization of human reproductive rights.

BIOETHICAL CONFLICTS BETWEEN MOTHER AND FOETUS

Does a pregnant woman who has made a decision to become a mother, have a moral obligation to change her life in a way which would minimise the possibility of her child being born ill? It is quite obvious that an expectant mother's life style and behaviour can have a negative influence on the wellbeing of her foetus. For example, unbalanced diet, smoking, use of alcohol or drugs can have a damaging impact on the foetus. Genital and somatic diseases of the mother can create an additional risk. For example, there is a high probability of foetal pathology in the cases when a woman with diabetes mellitus does not carry out careful control of the glucose level in her blood during pregnancy.

If an expectant mother shows readiness to modify her life style during pregnancy and to tolerate inconveniences related to it, is she also morally obliged to agree to some invasive medical manipulations for the sake of her foetus's wellbeing? For example, if she is informed by a doctor that she needs a Caesarean section because of certain indications connected with the state of the foetus, is she morally obliged to agree to the operation and expose herself to pain and risk related to it? In another clinical situation a doctor can tell the woman that there are indications for a intra-uterus operation with the purpose of improving the medical state of the foetus. The decision naturally depends on the efficiency of medical technology, the risk for the mother and the extent of the need in the operation for the foetus. However, let us assume that in a concrete case the doctor is convinced that a woman behaves in a morally unacceptable manner. If additional information and elucidation does not result in the woman's consent to the medical manipulation, which her foetus presumably needs, is it necessary to convince the woman, violating the principle of respect for autonomy? If the

attempts to convince her to make the right decision also bring no result, is it possible to use compulsion?

An expectant mother's moral obligation to avoid harming her foetus as an "unborn child" should be balanced with a great number of other moral circumstances which make up the moral content of her life. In any case, a doctor, who supposes that a pregnant woman does not act in the best interests of her foetus is confronted with a moral dilemma.

Difficult bioethical problems come into question in the context of critical situations in the mother and foetus relationships. For example, in the case of conflict between the lives of the mother and foetus a problem of therapeutic abortion comes up. The supporters of therapeutic abortion consider it possible because it is ethically permissible to make a good action (rescue the mother's life), even if it has a negative consequence, which is not its direct purpose (the death of the foetus). But the opponents of the therapeutic abortion object: "*non sunt facienda mala ut veniant bona*" ("one should not do evil which results in good").

Medical indications to therapeutic abortion change with the development of medicine. The indications described in the treatises of classic medicine have almost lost their force, as the modern medicine can stabilize and successfully treat many illnesses. Lung tuberculosis, cardiopathy and other diseases of the cardiovascular system, eclampsy, haematological diseases, diseases of kidneys, liver and pancreas, serious forms of myasthenia, and tumours once were indications to therapeutic abortion. Presently cases in which the termination of pregnancy is really needed are rare. The situation in which the continuation of pregnancy, on one hand, threatens the mother's life, and on the other, the rescue of the child is not guaranteed, while an abortion can save the mother's life, is defined as the "principle of the foetus second-rate importance". In this case abortion is only an acceleration of its death with the purpose of rescuing the mother's life.

In the cases when a woman's death is inevitable, an attempt of rescuing the foetus is undertaken (for example, Caesarean section is made to rescue the life of a dying woman's child). This is named "the principle of the mother's second-rate importance".

If we unite both these principles, in every case it is ethically correct to estimate the possibility to help the mother and the child as a single task. Even if complete success is improbable, it is necessary to try to attain the maximally possible effect. If it is impossible to save both the mother and child, the more probable variant is chosen.

The development of perinatal medicine resulted in the appearance of new ethical problems. The methods of prenatal diagnostics of the child's gender and a number of inherited and innate diseases are widely available now. The application of such methods allows to prevent the birth of incur-

ably sick children. However, this approach to terminating the pregnancy with defective foetus is often called eugenic abortion.

The diagnosing of grave hereditary and innate diseases in the foetuses and the termination of such pregnancies prevents the hard life of disabled people and diminishes the psychological and economic burden on the family and society. The development of medical-genetic methods of diagnostics and treatment can be instrumental in the prevention of serious illnesses and alleviation of many people's suffering. At the same time, many religious and public figures speak about the ambivalent nature of the prenatal diagnostic methods of hereditary diseases at the early stages of foetation. They point out that some of these methods can be risky for the life and integrity of tested embryo or foetus. The diagnosing of an incurable or hardly treatable genetic disease often becomes a motive to terminating the engendered life; cases are known when the parents were exposed to corresponding pressure. Prenatal diagnostics can be considered morally justified, if it is aimed at the treatment of diagnosed diseases at the earliest possible stages, and also at the preparation of the parents to special care which a sick child needs. Everybody has a right to life, love and care, regardless of having one or another disease. J. Sudo considers that from the ethical point of view, inferiority changes nothing in the ontological essence of the future child — the same as every other invalid he/she should not be eliminated from the society because of his ailment, but rather should get its greater help and protection. Eugenic abortion is reprobated by religious denominations as a variety of "felonious homicide". From the legal positions, eugenic abortion also can not be justified, foremost, because the international norms guarantee the observance of the disabled children's rights. Thus, the "Convention on the Rights of the Child" provides the right of a disabled child to special care. In addition, disabled persons, both adults and children, have equal rights with other people. The "Declaration on the Rights of Disabled Persons" of the General Assembly of UN (1975), and the "Declaration on the Rights of Mentally Retarded Persons" of the General Assembly of UN (1971), according to which invalids and mentally retarded people have the same right as other people.

Eugenics (from the Greek *eugens* meaning "pedigree") is a term, suggested by Frances Galton in 1883, it designates scientific and practical activity aimed at the improvement of cultural plants and breeds of domestic animals, and also at the protection and improvement of the human heredity. In the course of time the word "eugenics" began to be used only in the last sense. Eugenics is defined as the "social management of human evolution". We can distinguish positive and negative eugenics. The purpose of positive eugenics is to increase the reproduction of individuals with qualities, which can be considered valuable for the society — such as high intellect, good

physical development or biological adjustment. Negative eugenics aims at decreasing the reproduction of those who can be considered mentally or physically underdeveloped or who's development is below the average. In the last decades many basic pre-conditions of eugenics were scientifically discredited, and the eugenic movement has lost its influence as a public force. At the same time, due to the modern achievements of the medical and biological sciences and technologies, some aims of eugenics were partly transformed and attained. For example, the medical-genetic consulting helps the future parents if there are reasons to fear that their child will inherit a serious hereditary disease. Having estimated the risk, the married couple can make a decision as to the conception, continuation or termination of pregnancy. Surely, the absence of considerable physical and mental defects and the presence of good health in the offspring are worthwhile aims of the medical science and practice.

Early diagnostics of the child's gender is widely used in the medical practice for the prevention of the birth of children with X-coupled hereditary diseases. However, the use of this medical accomplishment as a means of enabling the parents to determine the gender of their future child at their will can result in catastrophic consequences for the humanity. This is related to the fact that most peoples tend to prefer male children. The possibility of free diagnostics of the future child's gender at the early terms of pregnancy will create a threat of the female foetuses discrimination. Legal barriers should be created to such attitude.

The right to dispose of one's fate is an appropriate socially-historical process, one of the leading tendencies of the modern time. It is naive to suppose that a modern civilized woman will disclaim her right to family planning or the possibility to give birth to a healthy child, and would take a position of complete obedience: "all will be as God wishes". Modern medicine must defend the ideas of justice, equality of people, value of their life and health, and humanism. The development of the medical science must be estimated from the perspective of morals and good sense.

BIOETHICAL PROBLEMS OF THE USE OF NEW REPRODUCTIVE TECHNOLOGIES

New reproduction technologies have made an important contribution to the solving of the infertility problem, but they have also created new important and difficult ethical problems for the society to solve. The concept of "reproductive technologies" is used to denote the manipulations carried out with the purpose of replacing different stages of the natural reproduction

process, of which the major stages are sexual intercourse, tube fertilization, implantation in the uterus and subsequent endometrial gestation.

The artificial (auxiliary) fertilization is a procedure which replaces sexual intercourse as the means of achieving the internal fertilization. The artificial semination is used for a long period of time with the purpose of overcoming masculine infertility by using the husband's or donor's sperm. A sperm donor can be used in the cases when the husband possesses inferior sperm or is a transmitter of a hereditary disease. An ethical problem is created by the use of artificial semination with donor sperm for the voluntarily achievement of positive eugenics aims. The supporters of this technology suggest to create banks of sperm received from men, "prominent" in different aspects. Married couples can use the desired sperm for the artificial semination of the wife. Another ethical problem of artificial fertilization with the use of donor sperm is a possibility of this method application by unmarried women. However, the greatest ethical contradictions are caused by the use of artificial semination in the context of substitute maternity. The so-called substitute mother agrees to artificial semination with the sperm of another woman's husband in order to bear and deliver a child for this married couple.

The fertilization of in vitro consists in the procedure when the husband's (or donor) sperm is united at a laboratory with the wife's (or donor) ovule, received from the woman by laparoscopy. After the laboratory fertilization an embryo is cultivated to the 8-cellular stage and is inserted in the uterus for implantation. This reproductive technology is very complicated and the frequency of positive results can not be considered acceptably high. An important step in the technical improvement of this method was the selection of a few (up to 10) ovules, their fertilization and freezing of embryos at the 8-cellular stage. In future they are unfrozen at necessary moments by turns are and used during a few months until a successful implantation is achieved. An ethically difficult question is how to act with the "superfluous" embryos. Unfortunately, the freezing of an non-impregnated ovule presents a more intricate technical problem. The technology of fertilization of in vitro in combination with the embryo transfer is used for the therapy of infertility, for example, caused by the oviducts obstruction.

The reproductive technology of fertilization of in vitro with subsequent embryo transfer to the uterus replaces not only sexual intercourse but also the oviduct fertilization. However, there is a future possibility of the substitution of other stages of natural human reproduction — the implantation and endometrial gestation. There are no technical obstacles for the fulfilment of the task of complete artificial gestation in an artificial uterus cavity. This prospect causes ethical problems, especially from the position of religious ethics. ***Artificial gestation or ectogenesis*** in the complex with the

preceding in vitro fertilization will make a complete system of reproductive technology, in which every element of the natural reproduction process is effectively substituted.

The use of the so-called *intra-oviduct gametes transfer* helps to achieve successful results more frequently than in the treatment of infertility with the method of fertilization in vitro in combination with the embryo transfer. Ovules are placed together with spermatozoa in one (or both) oviducts, where the fertilization takes place in natural conditions (in vivo). Unfortunately, the increased risk of extra-uterine pregnancy should be taken into account.

The improvement of the results of infertility treatment is achieved also by the use of the new reproduction technology of ***intra-oviduct zygote transfer***. The essence of this method consists in the introduction of a one-cell zygote, received by laboratory fertilization of in vitro, in an oviduct.

The reproduction technology of *intra-cytoplasm spermatozoon injection*, which became common enough in the clinical practice, was developed in 1992. To achieve the fertilization, a single spermatozoon is injected in an ovule in laboratory conditions. This method is directed at overcoming the masculine infertility. Even a man with a very low number of spermatozoa in his sperm can become a biological father if this reproduction technology is used. It allows a married couple to avoid ethical and psychological problems caused by the use of donor sperm.

The ***pre-implantation genetic diagnostics*** is an important modification of the in vitro fertilization technology. It consists in the investigation of the embryos received by laboratory fertilization *in vitro,* for the presence of chromosomal or molecular hereditary diseases before they are implanted. The use of fertilization in vitro technology in the combination with pre-implantation genetic diagnostics in married couples which have a high risk of genetic diseases transmission, removes the ethical and psychological problems of selective abortion on the basis of standard methods of prenatal diagnostics.

There is a reproduction technology, which can be used in the situation of female infertility, when a woman has no ovaries or they are functionally inferior. If the uterus functions normally, it is possible to impregnate a donor ovule with the husband's spermatozoon in vitro and to transfer it to the wife's uterus cavity for implantation and gestation. In this case the husband is the child's genetic father.

Another situation is possible: a woman's ovaries function normally, but her uterus is inferior or absent. In this case the reproduction technology can help the woman to become a genetic (but not gestational) mother by the use of ***substitute maternity***. The fertilization of the wife's ovule with the husband's spermatozoon is carried out *in vitro*. Then the embryo is inserted in

uterus of a substitute mother, who has consented to bear the child for the married couple. The substitute mother will be the gestational but not the genetic mother of the child.

All the mentioned reproductive technologies are connected with a number of ethical problems, some of which were already mentioned or discussed.

Infertility in the family is a serious psycho-trauma for its members. Many patients who turn for medical help apperceive the situation in their family as a kind of punishment, in most cases — undeserved, to their opinion. Should a doctor take the responsibility for promoting the pregnancy and its subsequent management to the time of birth? This is one of the basic questions of the procreation bioethics. On one hand, the modern medicine, as a rule, is quite capable of coping with these tasks. On the other hand, the physicians should be confident that children born as a result of extracorporeal (*in vitro*) fertilization will not differ from the children conceived in the natural way.

The World Medical Association has a positive attitude to the new reproductive technologies, because they serve a noble purpose — to treat infertility and grant the couples, deprived of the possibility to procreate, the opportunity to have children. In 1987 in Madrid the "Statement on In-vitro Fertilization and Embryo Transplantation" was approved. It specified that reproductive technologies are ethically justified in the infertility unresponsive to medicinal and surgical treatment, especially in cases of immunologic incompatibility, irreversible obstacle to contact between male and female gametes and infertility for unknown cause. The statement observes that the physician can only act with the full informed consent of donors and recipients, in accordance with all the applicable legal and ethical norms. The patients are entitled to the same confidentiality and privacy as is required with any medical treatment. When IVF techniques produce excess ova which will not be utilized for the immediate treatment of sterility, their use must be determined in agreement with the donors (excess ova can be: destroyed, cryopreserved, fertilized and cryopreserved). Physicians should refrain from intervening in the reproduction process for the purpose of making a choice as to the foetus' sex, unless it is to avoid the transmission of serious sex-linked disease. Any commercialization by which ova, sperm, or embryo are offered for purchase or sale is expressly condemned by the Statement. It says that the physician has the right to refuse any intervention he or she deems unacceptable. The problem of the choice of the donor of sperm, his anonymity, rights and duties is especially important. The following terms are regulated: only men who have children can be donors, in vitro fertilization is conducted only on medical indications and only for heterosexual couples, all donors are investigated for the presence of diseases transmissible in the sexual way.

New reproductive technologies in many cases allow to overcome the ailment of sterility. At the same time, the widening of technological interference with the process of human life conception, in the opinion of different religious denominations, presents a threat to people's spiritual integrity and physical health.

Article 48 of the "Bases of Legislation of Ukraine on Health Protection" says: "The application of artificial fertilization and embryo implantation is carried out in accordance with the terms and in the order established by the Ministry of Health of Ukraine, at the request of a capable woman, who undergoes this procedure, on the condition of the presence of her husband's written consent, provision of the donor's anonymity and keeping the medical secret. The disclosure of the donor's anonymity can be carried out in the order provided by law".

On the grounds of our own observation, we consider that in most cases the treatment of infertility, including the use of reproductive technologies, is absolutely justified. As a rule, people of the late reproductive age apply for help in sterility. It is necessary to take into account that women extremely rarely turn to reproductive technologies at once; for many years they are treated for infertility in other ways, and only when the treatment does not render positive results, they agree to reproductive technologies. As a rule, the average age of women, who agree to in vitro fertilization in Ukraine is 36.4 years (V. M. Zaporozhan, 2001).

The modern level of development of medicine allows to create and support pregnancy even in the women during the period of menopause. Certainly, it is for parents to decide whether to give birth to children at their age. Taking into account the average time of life, there are no guarantees that parents will be able to rear the child to adult age. On the other hand, does a doctor have a right to refuse to help a woman in her late adulthood, who has lost her children, for example, as a result of accident? Should a doctor refuse an elderly woman in the donation of an ovule if she wants to bear a child with a new spouse? Is the refusal of donation in such cases the same as a refusal in treatment? Does a doctor have a right to do it? Does he violate the patient rights by the refusal? Certainly, the age of women who use reproductive technologies should be limited. Presumably, it is necessary to take into account the average time of life in every concrete country. The latest age for this procedure can be calculated as follows: the average time of life minus 25 years. The reasonable age limitation would be 45 or 50 years.

A special place in the issues of new reproductive technologies belongs to the "substitute maternity", which is not developed enough both in the legal and the ethical aspects. In the conditions when a family is sterile (for example, for the lack of uterus in a woman), this method of procreation has a

right to existence, although the ethics of substitute maternity is exposed to doubt. The necessity of the legal control and the ethical regulation of every stage of substitute maternity is dictated by the danger of commercialization of procreation. If we speak of the practice of substitute maternity, additional causes for its ethical estimation are as follows:

— psychological problems of a child born by a substitute mother;

— the possibility of negative influence on the family members relations;

— psychological and legal problems of the relations of the family with the substitute mother if she raises claims for the paternal rights to the born child.

In Ukraine there are no legislative acts which regulate substitute maternity. However a bill "On Reproductive Rights and Guarantees of Their Realization" offered to discussion, formulates the conditions of consolidating the rights of the citizens of Ukraine to use the method substitute maternity on medical indications. This document provides both the biological and substitute parents' rights and duties. Legal conflicts can be caused by the biological parents' refusal to accept the child if some deformities or anomalies are diagnosed in it, by the refusal of the substitute mother to return the child to its biological parents, or by possible financial disagreements.

Another bioethical problem occurs in the pregnancy with more than one foetus in auxiliary fertilization. Multifoetation often causes difficulties in maturing and development. Children are frequently prematurely born with the symptoms of underdevelopment. The economic aspect should also be taken into account: the bearing of a multiple pregnancy, the support of weak or sick new-born infants' health requires serious financial expenses both from the parents and from the clinic. The necessity of elimination of one or more foetuses is obvious in the cases of serious anomalies of development and when the pregnancy can not be born at all or causes a risk for the mother's life. In the absence of such circumstances selective elimination can be considered as a variety of abortion (then its ethical issues are in another sphere). A number of questions arise. What embryo should be destroyed? What method of elimination should be chosen? Is it necessary to resort to elimination if there is a real threat of the loss of pregnancy?

The donorship of gametes and embryos is one of the most discussed questions. Ethical, legislative and social problems connected with the donation of gametes and embryos rise in the majority of countries in the world. The 41th World Medical Assembly adopted the "Statement on Fetal Tissue Transplantation" (Hong Kong, 1989). The retrieval and preservation of usable tissue cannot become the primary focus of abortion. The World Medical Association affirms that the use of fetal tissue for transplantation purposes is still in an experimental stage and thus is ethically impermissible.

The main ethical opposition to the artificial fertilization is presented by the religious views. Artificial fertilization with the donor sperm is criticized in connection with the dissociation of the continuation of family process from the matrimonial relations. As this reproductive technology engages a third party (the donor of the sperm) in the matrimonial relations, it is considered by its ethical opponents as a form of breach of faith. However, even the artificial fertilization with the husband's sperm does not avoid criticism. Some specialists in religious ethics assert that any procreation out of the limits of personal sexual relations is amoral, and express doubt in the morality of receiving ovules, fertilization *in vitro* and other reproductive technologies. Ethical opposition of fertilization of in vitro (and contiguous technologies) is based also on the argument of the "unnaturalness" of this method, which conduces to dehumanisation and depersonalisation of the procreation. The accusations in the "factory" or "incubation" production of children have the same grounds.

Less radical ethical opposition accepts the use of fertilization *in vitro* with the embryo transfer in the context of matrimonial relations but with no intervention of a third party donorship of sperm or ovules or substitute maternity.

One of the most questionable issues is the donor anonymity. In Ukraine, as well as in the majority of countries in the world, the donor remains anonymous. The information about donors is divided into identifiable and unidentifiable. Unidentifiable information includes: the complete physical description, conclusions of medical specialists, information about the social status (education, profession), ethnic belonging, number of children conceived in a natural way (for men). Identifiable information: complete passport data, date of birth, address, results of concrete research, information about the revealed pathology. Usually the unidentifiable information about donors is given to the recipients in a kind of donor passport. The copy of this passport is added to the patient's case history.

For many cultures and religions the donorship of gametes is unacceptable. For example, in the Islam it is considered that the problem of long absence of children in a family should be solved within this family, i.e. without the use of donor sperm or ovule. Otherwise both the genealogy and the genetic code of the family is violated. In many religions the donorship in the issues of pregnancy (the use of donor sperm or ovule) is considered as an unusual form of adultery, because in both cases it is not clear who is the veritable father or mother of the future child.

One of the ethical problems of fertilization in vitro and contiguous technologies is the destroying of embryos, unnecessary or unsuitable for implantation. This problem is especially serious for the specialists in ethics, who acknowledge the moral status of an embryo. The problem is partly

solved by the technology of freezing the extra embryos, but sometimes this approach causes new problems. The moral acceptability of using the embryos in research aims is an independent ethical question.

The ethical problems of the gametes donorship to be discussed include the impermissibility of commercialization of gametes and embryos donorship. The questions of cryopreservation of gametes and embryos also need discussion, as to who should decide the fate of unused embryos (probably only the biological parents should make the final decision). The possibility to use the gametes of people who have dyed for the birth of children from them is known. The ethical views on this problem are also ambiguous and require revision. Should a child receive information that he/she is from a donor? On one hand, it can cause his/her alienation from the family, but on the other — everybody has a right to exhaustive information concerning him/herself.

The ***pre-implantation genetic diagnostics*** gives the married couples with a high risk of serious genetic diseases transmission a possibility to prevent the constantly repeated spontaneous abortions and termination of pregnancy on medical indications. The fact that the application of pre-implantation genetic diagnostics can result in the selection of embryos at the early stage of their development, caused serious debates about this kind of diagnosing as a potential mechanism of eugenics. This kind of practice is possible only in countries, where the development of reproductive technologies allows to render the complete spectrum of medical treatment, including the intra-cytoplasm spermatozoon injection.

Section VII
THE CONTROL OF GENETIC TECHNOLOGIES AND MODIFICATIONS OF THE HUMAN NATURE

"Genetics is the philosophy of the modern medicine."

N. Bochkiv

BIOMEDICAL ETHICS OF GENETIC RESEARCH, CONSULTING AND SCREENING OF THE POPULATION

Bioethical Problems of Medical Genetics. The rapid development of the genetic science opened before the humanity unlimited possibilities of diagnosing and treatment of many hereditarily conditioned diseases, discovering the mechanisms of senescence and prolonging the life-span. The accumulation of exact information about the human genome will enable the specialists to forecast the probability of serious acquired diseases onset. In the near future the pre-conception prognosis of the height, colour of eyes, intellectual and behavioural features of the future human being will become possible. At the same time, the practical application of genetic research causes a number of scientific and bioethical problems. The possibilities of genetic diagnostics are far ahead of the progress in the field of radical treatment of genetically conditioned diseases. The nascent dilemmas concern both the personality of the patient, his/her family and public relations, and the religious morals. Difficult questions arise concerning the possibility and willingness of a patient to know about the high probability or inevitability of some dangerous or mortal disease developing in him in future. The questions also concern the cases in which it is necessary to inform a person about the genetic defects discovered in him/her, and whether a doctor is obliged to inform the family members about his patient's genetic pathology.

In the context of medical-genetic consulting there are traditional bioethical problems, which concern the abortion, the regulation of reproduction, the patient's informed consent, confidentiality, supporting therapy and social justice in the distribution of the limited resources of health protection.

The question concerning the nature of co-operation between a doctor-geneticist and a patient and his/her family is complicated. A point of view exists that the information the doctor provides should not be directive, and that he/she should not try to impose his moral views on the patient. The doctor should simply give scientific, social and psychological information to the patient and let him/her and his family make their own decision. However, such a neutral position is more and more called in question. Actually, the doctors-geneticists can not remain totally neutral, especially in regard to the ethical choices, which they consider to be undoubtedly amoral. To preserve their autonomy in decision-making, the patients should discuss the ethical problem with other specialists, especially with those, whose opinion on this issue is opposite to the first specialist's.

The medical-genetic consulting has passed to a new, higher level when the programs of genetic screening were introduced. The conducting of mass blood or other biological samples testing with simple inexpensive technologies allows to carry out effective early diagnostics of hereditary diseases. The first mass screening was successfully conducted among the black Americans with the purpose of diagnosing the sickle cell anaemia (sickle cell disease, Tey-Sachs disease) in the Jewish communities. Later excellent results were achieved with the introduction of the population screening for phenylketonuria, mucoviscidosis and hypothyroidism. Nevertheless, this did not remove certain prejudice in regard to genetic screening and its estimations as an instrument of eugenics.

During the last years the specialists have proved the possibility of specific genetic testing for the identification of people who have high risk of developing breast and large intestine cancer. The regular monitoring of such people allows to conduct the diagnosing of the tumour at the early stages.

The carrying out of screening research which involves a great number of people makes the problem of keeping the medical secret important. The possibility of pre-clinical diagnostics of diseases will be accompanied by the growth of the number of third persons interested in the access to the results of genetic research. They, foremost, include medical insurance companies and employers. In this situation the violation of confidentiality and discrimination on genetic grounds become probable.

The methods of prenatal diagnostics, which allow to discover a hereditary illness at the early stages of prenatal development, have ambiguous consequences. Some of these methods can present a threat to the life and integrity of the tested embryo or foetus. The discovery of an incurable or difficultly curable genetic disease quite often becomes a motive for termi-

nating the engendered life; cases are known when moral pressure was exerted on the parents. Prenatal diagnostics can be considered morally justified if it is aimed at treating the diagnosed pathological states at the earliest possible stages, and at the preparation of the parents to special care which a sick child needs. Everybody possesses a right to life, love and care, regardless of the diseases he/she may have.

Thus, the bioethical problems of medical genetics can and must be considered from the positions of the principles of respect for autonomy and informed consent, as well as trust and veracity in the doctor-patient relations. It is necessary to follow the principle of social justice in the distribution of limited medical resources the society possesses in regard to applying expensive scientific medical technologies. Non-interference in the private life and the observance of confidentiality in the relations between the doctor and patient also are necessary conditions. The problem of confidentiality is related to the necessity of discussing and solving the followings practical issues, existing in the field of medical genetics:

1. Observance of the confidentiality of medical documents in the process of observation of a patient and implementation of medical and biological research;

2. Access restriction to medical information and exception of the possibility of manipulations on the part of insurance companies and employers;

3. Development of standards of granting the information on hereditary diseases to the family members;

4. Protection of the genetic information by encoding and anonymity of the DNA samples taken in the process of inspection and treatment of a patient or with a research purpose.

Successes in the decoding of the genetic code create real pre-conditions for wide genetic testing, discovering the information on every person's natural unique features and his/her predisposition to certain diseases. The creation of a "genetic passport" can help to prevent the development of high risk diseases in a concrete person if the received information is used reasonably. However, there is a real danger of misusing the genetic information, in which it can serve to different forms of discrimination. In addition, the possession of information concerning the hereditary predisposition to severe diseases can become an exhausting moral burden. Therefore genetic identification and genetic testing can be carried out only on the basis of respect for individual freedom.

The moral-ethical and scientific-practical problems of genetic research interlace very closely. As the human genome is charted and the availability of genetic research increases, the necessity of establishing the diagnostic validity of tests grows. This is a very difficult task because of the genetic heterogeneity of the hereditary diseases. An important scientific problem which requires long-term research is the determination of diagnostic signif-

icance of the signs of genetic predisposition to the family forms of oncologic diseases, diabetes mellitus, and ischemic heart disease. The probabilistic pattern of genetic research results dooms a patient to uncertainty, which can lay a negative imprint on all his/her further life.

The international regulation of genetic research issues is carried out on the basis of a number of important documents, which are recognised and practically applied in different states of the world. The Statement on Genetic Counseling and Genetic Engineering, adopted by the 39th World Medical Assembly (Madrid, 1987) and rescinded in 1992 and at the WMA General Assembly, Santiago 2005 is one of such documents (Supplement 13). The provisions of this Statement concern the genetic counselling and gene engineering. It is called to help the doctors in working out the ethical and professional problems in the field of medical genetics.

The World Health Organization (WHO) has generalized the international experience of solving ethical problems, which arise during the medical-biological research in 1995 in the "International Guidelines on Ethical Issues in Medical Genetics and Genetic Services". This document contains the main provisions on rendering medical-genetic help with the purpose of helping the people with genetic pathology to live and have normal children. The fundamental ethical approaches presented in it are as follows:

— equal and impartial distribution of public facilities among those who need them;

— freedom of choice based on complete information. During the realization of the reproductive choice a woman must have a right to the final decision;

— genetic screening and testing should be voluntary, not mandatory, the pressure on the part of the government, society, medical workers or others should be excluded;

— consideration of distinctions between people and of the opinions of those who are in the minority;

— respect for the client's intellect regardless of the level of his knowledge;

— teaching the population, physicians, teachers, and priests the bases of genetics;

— close co-operation with organizations which unite the patients with genetic illnesses and their family members;

— prevention of discrimination or favouritism based on genetic characteristics in the employment, insurance or teaching;

— complex solving of problems with other professionals, including the medical workers of different specialities, social workers and others; if possible, involving the clients in the discussion of their problems as informed participants of process of decision-making;

— use of undiscriminating terms, respect for the patient's personality.

In 1997 the General conference of UNESCO at its 29th session has adopted "The Universal Declaration on the Human Genome and Human Rights" (Supplement 14). This Declaration was aimed at preventing such use of genetic information which would violate the fundamental human rights and freedoms, humiliate the human dignity, or pursue the object of public isolation of separate individuals, families, groups, or communities. The Declaration stresses that the genetic information obtained in the research of different biological samples is all the more important for the life of the society. The number of genetic data banks grows in the world, and some states conduct the genetic census of the population. Considering the rapid and not always organized growth of this field of scientific knowledge it is necessary to develop unified ethical principles and guidelines.

The Declaration accepted by UNESCO is not a legally obligatory document, and this enables the states to adapt its positions in accordance with various situations and new scientific discoveries. The Declaration determines the principles which the states must follow in the process of perfecting their legislation and policy in this field. The Declaration calls to the collection, treatment, use and storage of genetic material on the basis of transparent and ethically acceptable principles. It suggests the establishment of independent, multidisciplinary and pluralistic committees on the issues of ethics at the national, regional, local and institutional levels. The collection of material for genetic research must be carried out on the condition of obtaining the "prior, free and informed consent of the person concerned" and the investigation "shall not give rise to financial or other gain" to the person who is providing the genetic material. Exceptions are possible, but they should be permitted only in the order "prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights". The Declaration confirms the right of a person to abolish his/her consent if the research "does not have an expected direct health benefit". The right to the information on the results of the research is also regulated in the Declaration, which recommends that culturally adapted and protecting the interests of the examinee consultation should be provided in this field if the results of the genetic research can have substantial value for the examinee's health.

Confidentiality is the basic question at the stage of the obtained genetic information processing. The Declaration provides that the information on the genetic data related to the tested person should not be shared with third parties, in particular — with the employers, insurance companies, educational institutions and families. An exception can be made only on the behalf of society and only in cases provided by the legislation and in accordance with the international law.

At the stage of using the results of genetic research one of the basic moral-ethical problems is the change of the objective of research. The Declaration states that the information collected for one purpose must not be used for other purposes which are incompatible with the primary intentions.

The Declaration recommends to take proper measures in the field of education, teaching and public information and calls to join the bilateral and multilateral agreements, which allow the developing countries to extend the possibilities for their participating in the creation and exchange of scientific knowledge on the human genome. The purpose of the International Committee of UNESCO on Bioethics and the Intergovernmental Committee on Bioethics is the assistance in the implementation of the Declaration and the spreading of the principles which this document expounds.

The process of integration of Ukraine in the European community promotes the necessity of perfecting the legislative regulation of the biomedical human rights. A new legal act on the defence of the human genome according to the norms of the international law must be passed. The basic document used by the European Council, directed at the protection of human rights and freedoms in connection with the use of the accomplishments in biology and medicine is 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, adopted on April 4, 1997 (see Supplement 5). The preparation of project of this Convention began in 1990 by a specially created Committee which was reformed into the Leading Committee on Bioethics in 1993. By now more than 30 countries out of the 42 members of the European Council have joined the Convention. Ukraine signed it in March, 2002.

The Convention concerns the human rights involved in genetic research, cloning and introduction of gene therapy. The Convention proclaims the prohibition of any forms to discrimination on the grounds of the genetic research results. The prohibition includes discrimination on the grounds of gender, race, colour of skin, language, religion, political and other beliefs, national or social origin, belonging to the minorities, property position, genetic heritage, etc.

It is necessary also to respect the right to stay uninformed. Genetic tests can be made only after obtaining a voluntarily and conscious consent of the examinee and must be accompanied by appropriate genetic consultations. The Convention does not provide any limitation of the right to carry out diagnostic interference at the stage of embryo in order to define the possible presence of genetic predisposition to serious diseases in the future child.

The Ukrainian legislation corresponds to the propositions of the Convention in general, but the mechanisms of the laws implementation are not perfect yet.

Bioethical Aspects of the "Human Genome" Project. The largest biological project in the history of the humanity was started in 1990, it planned the decoding of all genes during a protracted period of time, which was originally estimated as one century. However, in 1999 after the decoding of a greater part of the genome a prognosis was made on the possible complete decoding of the human genome by 2005. The activities of the 20 countries in the world, which participate in this project, are co-ordinated by the World Genetic Data Bank. An international organization HUGO (the Human Genome Organisation), which has united the countries possessing the front-rank biotechnologies, was created. The USA has allotted 3 milliards of dollars for the development of the project, 5% of this sum — for the solving of the social and bioethical problems arising in the course of its realization. The greater part of the investigations conducted in the "Human Genome" project are carried out in the USA. Russia, Japan, and the countries of Western Europe also take an active part in the project. The task of the project is to the chart and establish the sequence of about 80,000 genes and three milliards of nucleotides, of which the human DNA consists.

The realization of the project has a great value for the fundamental science, because it will deepen the knowledge about the organization and functioning of the human genetic apparatus considerably. The knowledge on the similarities and distinctions in the structure of the human and the primates' DNA will help to reconstruct the process of anthropogenesis more precisely. The complete decoding of the genome with the possibility of molecular-genetic diagnostics of the hereditary diseases will create a possibility of their prenatal diagnostics at the early stages of pregnancy. Even now such a possibility exists for phenylketonuria, mucoviscidosis, haemophilia, sickle cell anaemia and some other diseases. The importance of the genome decoding for the medical practice consists not only in the possibility of molecular-genetic diagnostics but also in the new prospects of gene therapy. The implementation of the "Human Genome" project is attended with the revolutionary rates of development of the molecular-genetic and contiguous biotechnologies, which find their application not only in medicine but also in the plants and animals selection, pharmaceutical industry and other fields.

However, the inevitability of ethical, legal and social problems caused by the realization of this project dictates the necessity of the detailed working out of the ethical aspects of research, further development of the normative positions related to the analysis of the human genome. The program of the European Community "The Analysis of the Human Genome" formulated the following bioethical pre-conditions of the research in this field:

— the right to genetic information concerning oneself is a component part of a person's rights; this principle is interpreted by the constitutions

and legislation of the states-members of the association as a component part of the human rights;

— considering the possible results of the human genome research, a single system must be developed, which would take into account the medical, ethical, social and legal aspects of these results use, and prevent their unacceptable use;

— the absence of clear standards and rules, which determine the concrete aspects of the possible development of the genome analysis generates a danger of attempts to intrude in the human genome with the purpose of making the genetic alterations hereditary, and to carry out genetic research with the aim of monitoring. Both attempts can have grave consequences for the society, so it is urgently necessary to perfect the preventive measures of unacceptable consequences;

— in the process of the program development there is a necessity of distinguishing reliable scientific information to be used by the political authorities as the basis for making consistent, clear and responsible legal decisions.

The "Human Genome" program is confronted with three basic problems of molecular-genetic research: the confidentiality of information on the results of research, the problems of mass screening, and the testing of patients. These global problems engender questions concerning the competence of using the genetic information (by employers, medical insurance companies, etc.); the reliability of confidential information storage in the data banks; the possibility to use the obtained information with non-medical purposes (in the judicial practice); patenting the genetic information, etc.

In a special declaration of the World Health Organization Assembly devoted to the Human Genome Project, which took place in September, 1992, the ethical and legal principles were presented as follows:

1. The genetic services must be generally available to avoid their use only by well-off people; this would increase the social inequality.

2. International information, technologies and knowledge exchange between all the countries is important.

3. It is necessary to respect the will of all screened persons and their right to decide on the questions of their participation and use of obtained information.

4. Full information must be given to the patient or his legal representative. The medical secret must be kept, and the information must not be given to any third parties without the patient's consent. Even if the patient's family members belong to the risk group, the medical secret must be kept, except for the cases when a family member can seriously suffer, and this harm can be avoided by disclosing the information. Confidentiality can be broken only as the "last measure", when the attempts to convince the pa-

tient to disclose the information have failed; even in this case it is possible to disclose only the necessary genetic information.

5. The granting of information to a third party or access to personal genetic information can be carried out only on the informed consent of the patient.

The characteristic tendency in the modern stage of the molecular-genetic research in the field of human genome is its commercialization. It involves the danger to the fundamental scientific value — the principle of objectivity of the scientific knowledge. Even now there is a growing number of private firms, which invest considerable resources in the development of the genome research, expecting to get grandiose incomes. Sharp discussions on the right to patent the human genes and nucleotide sequences, flaming up between the competitive participants of the genome research, are the result of deep deformation of the modern science. If we take into account that private companies had already invested many hundreds millions of dollars in the project development, their aspiration to receive a maximally possible gain from the realization of the project is quite understandable. In this sense the "Human Genome" project in a concentrated form reflects the forming of a new variety of science, which paradoxically combines fundamental research, production and commercial activity.

The "Human Genome" project creates an extraordinarily important precedent for the development of science and its collaboration with the public. For the first time the realization of a large international scientific project proceeds simultaneously with the research of its social consequences and the moral rules of its development. It is the first scientific project, in which the aspect of moral discussion has entered the context of scientific development from the very first steps. In the human genetics, same as in other branches of science, an important place belongs to hypotheses and theoretical models, which have not got sufficient empiric confirmation and theoretical grounding yet. They are the result of the necessary creative process of the advancement of hypotheses, which are afterwards exposed to "selection" in accordance with the scientific procedures of verification and exception of falsification. Some of them quite justly become the public property, being indicative of academic freedom and an exciting flight of creative imagination. However, it is necessary to remember that by becoming the phenomena of mass consciousness, scientific hypotheses get out of the control of the precise mechanisms of scientific "selection", acquire their own life, and begin to motivate and direct the social actions, ambiguous in their consequences. Scientists must realize their responsibility for the harm which can be done by a "stray" hypothesis, which was developed not carefully enough, or, moreover, an erroneous one. The development of the "Human Genome" project gave grounds for an unprecedented distribution

in the mass consciousness of an enormous number of hypotheses, some of which have a distinctly discriminatory and racist nature.

The present public hopes concerning the practical application and advantages of genetic research are, in the opinion of most researchers, too optimistic. The possibilities of practical medical application of the results of the human genome studies are significant, but it is very difficult to predict when they will result in a substantial progress in the clinical practice. Although the expenses connected with the use of molecular-genetic technologies are high, some practical aspects of their application proved to be economically efficient. Some results of the "Human Genome" project are widely used in the prenatal diagnostics, for example, of monogenic diseases. However in the near future it is hardly possible to expect serious progress in the field of malignant tumours and chronic diseases treatment on the basis of the knowledge about hereditary predisposition to them.

The patenting of the molecular-genetic research results is an objective reality, so it is necessary to develop an international conception, which would promote the stimulating influence of the results of DNA patenting and the economic progress by strengthening the contribution of the global research association to the creation and application of new medical technologies.

The molecular-genetic research and bioethical problems, with which it is connected, increase the need in the knowledge on these issues in all the strata of society, including the politicians, the employees of health and education institutions, and the representatives of mass media.

From the bioethical point of view, the central question is whether the purpose of achieving complete knowledge on the human genetic basis is an ideal, for which the people should strive, and whether this knowledge will not become an evil for the humanity.

Technological optimists see the possibilities of removing medical problems by successive intrusion in their genetic basis. This would allow to improve the health of the population and to decrease the expenses on health protection. On the other hand it is obvious that the diagnostics of the problem genes will promote the possibility of their removal and replacement. Therefore the opponents of the "Human Genome" project stress the possible increase of the rate of terminating pregnancy on genetic indications. The realists understand that many diseases are not genetic, and many of those which are related to the hereditary material are polygene, i.e. many genes are involved in their conditioning. This means that the researchers have to define the mechanism of genes coordination, which results in the origin of cancer, heart diseases, hypertonic illness and mental disorders. We can not exclude that the genes which increase the risk of some undesirable states are at the same time necessary for the prevention of other equally unacceptable processes.

MEDICAL-ETHICS PROBLEMS OF PEOPLE AND ANIMALS CLONING

In 1997 the world association faced the fact of successful cloning of a mammal, in which the nuclei of somatic cells were used. Sharp debates on the prospects and dangers of this scientific discovery started at once in the scientific, religious, and political communities. The idea of the possible use of this technology for the reproduction of human beings caused the greatest worry and rejection.

Cloning is the process of receiving genetically identical offspring by non-sexual reproduction. The term a *clone* originates from the Greek word "*klon*", which means a branch, sapling, or graft. This concept was used before to determine the vegetative reproduction of plants. Cloning of plants with grafts, buds or tubers was known in agriculture for over four thousands years. Since the 1970-s small groups and even separate somatic cells were widely used for the plants cloning.

The technical essence of cloning consists in taking a nucleus containing the chromosomal material from a cell of an organism and its implantation in an enucleated ovule or another cell of another organism. Such a modified cell possesses a potential for growth and development as a new organism which is a genetic copy of the original. An analogy is possible with co-twins, with the substantial difference, that a clone is able to observe its biological future within the limits of its genetic determinants. Surely, a person is more than an aggregate of genes. He/she is formed by the influence of his/her environment, time, place, and education. Therefore a genetic clone does not have a veritable identity with his/her genetic parent. However, the ethically problematical nature of cloning consists in the fact that this technology affects the bases of human nature and its rational control.

If we estimate the principle possibilities of cloning, we can say that in future it may be possible to produce multiple copies of people, which could be suitable for different purposes — such as warriors, intellectuals, or sexual producers. Without discussing the ethical details of such prospects, we shall only say that they are very remote. It is more probable that cloning will be used in agriculture, and in future — as a method of helping sterile couples, who wish to have their own child, or parents who want to have a genetic copy of a child who has died.

From the scientific positions the possibility of the human cloning is based on the successes in the cloning of mammals with the use of the nuclei of germinal cells reared in a culture on an artificial nourishing medium. The use of somatic cells of mature animals was the next step. The first official information on the cloning of mammals (sheep) concerned the work per-

formed by a group of researchers directed by Ian Wilmut*. The nuclei were taken from the suckling gland cells of a mature sheep. In Japan the cloning of cows was carried out with the use of the nuclei of epithelial cells contained in the beestings (F. Golden, 1999). An unprecedented experiment on the mass cloning of cattle began in China, where the appearance of 20 to 50 cloned calves is expected. Australia, Canada, the USA, Great Britain and a number of other countries also participate in this project.

A substantial problem of cloning is a relatively high percent of spontaneous abortions at the late stages of embryonic development and frequent cases of death of animals soon after birth, especially when somatic cells served as the nuclei donors. Somatic cloning can be a reason of innate developmental anomalies. A number of cloned animals including the first cloned sheep had the phenomenon of early senility. The influence of cloning on the functional features and fecundity has not been studied yet.

It follows from the facts mentioned above that the cloning of adult mammals is not developed well enough in the technical and methodical aspects, so it is too early to raise the question as to the realization of the human cloning project. Depending on the purpose, cloning can be subdivided into cloning directed at the reproduction of human beings (reproductive cloning) and cloning for medical aims (therapeutic cloning). The main direction of the therapeutic cloning is the research in the field of stem cells obtaining.

The so-called therapeutic cloning presupposes the cloning of embryos at the early stages of development, which will act as a kind of banks of donor tissues for concrete individuals. Stem cells with their unique possibilities and potential to be differentiated into any tissues and organs became an object of scientific research long ago. An important feature of the stem cells is that in their transplantation they cause immunologic reactions of intolerance to a much smaller degree than donor organs and tissues. This approach in the prospect can result in the possibility of growing the predecessors of different organs and tissues in the laboratory conditions and then transplanting them instead of donor organs. In addition, the research is carried out on the use of the stem cells as vectors for gene therapy.

The human cloning, besides scientific and technical problems, involves complicated ethical issues. Firstly, the development of a human being as a personality is based not only on his/her biological heredity, it is also directed by the family, social and cultural environment. In the reproductive cloning

* In 1995, Ian Wilmut, Keith Campbell and colleagues created live lambs — Megan and Morag — from embryo derived cells that had been cultured in the laboratory for several weeks. This was the first time live animals had been derived from cultured cells and their success opened up the possibility of introducing much more precise genetic modifications into farm animals. http://www.ri.bbsrc.ac.uk/public/cloning.html

of an individual it is impossible to recreate all the terms of education and teaching, which had formed the personality of his/her prototype (the donor of the nucleus). Secondly, in the agamogenesis the initially rigidly programmed genotype predetermines less various interrelations of the developing organism with the changing environmental conditions (as compared to the sexual reproduction, when two genomes participating in the forming of an individual interact with each other and with the environment in a complex and unforeseeable way). Thirdly, both the reproductive and therapeutic cloning of human beings is involved in an irreconcilable contradiction with the religious morals. Practically all the religious denominations insist on the unnaturalness of the process of human and animal cloning. The representatives of the Orthodoxy Church in the whole world remain faithful to the strict understanding of the sacral nature of the human life: everybody is created as a unique personality "in the image of God". Therefore the great majority of specialists in the Orthodoxy ethics insists that all forms of eugenics, including the manipulations with the human genetic material with non-therapeutic aims, are disgusting in the moral aspect and threatening to the human life and wellbeing.

Vatican made a statement on the unacceptability of interference with the processes of reproduction and with the human and animal genetic material. The Mufti of Egypt and the head of the Copt Church spoke out that this type of scientific activity conflicts with the moral principles and divine laws.

The introduction of the reproductive human cloning can result in the destruction of the traditional moral foundations and, foremost, of the family. In addition, this situation is fraught with the origin of a number of socially-legal collisions. The relationships between people and clones, legal and property status of the clones, the possibility of considering a cloned person and his/her clone as a family — this is only an incomplete list of questions which will become actual after the introduction of cloning. All these legal collisions can cause serious changes in the constitutional, civil and other fields of law. We should note the fact that the majority of scientists-geneticists who have a critical attitude to the possibility of cloning, see the basic moral problems in the unsolved methodical questions of human cloning.

There is also a number of psychological problems related to the reproductive cloning. It is hard to forecast the impact of cloning on the human identity if a clone is a twin of the father or mother, born in the next generation and in a different environment. There are questions whether a clone will feel that he/she is only a copy of a person, who had existed already, that he/she does not possess an identity of his own.

Deep bioethical problems exist not only in the field of reproductive cloning but also in the therapeutic cloning. The technical possibility of receiving organs and tissues for transplantation will result in additional stratification

of the society with the selection of a class of people who will be able to afford them.

The principle question is whether the manipulation of people with the process of life itself is ethically acceptable.

Presently it is quite obvious that the ethical side of the problem of cloning has not been developed yet, and it probably will not be resolved in the near future. In spite of numerous reports in the mass media about the accomplishments in the reproductive cloning of human beings, the majority of researchers agree that for the present we can speak of it only theoretically. In fact, the question concerns not even cloning but obtaining a copy of a separate individual, because the term "cloning" presupposes producing a number of copies. Today the probability of negative consequences of this procedure considerably outweighs its benefits, therefore the answer to the question as to the expedience of continuing the works in this direction requires careful considerations. Possibly in some time, when all the stages of this difficult biotechnological method are improved, scientists, sociologists and other interested persons will return to the discussion of the expedience of human cloning. In any case, the solution of the questions concerning concrete people's cloning will be regulated by strict rules and, possibly, limited only to certain medical problems, such as sterility resistant to all the other methods of treatment.

The work with domestic animals is very important from the practical point of view. The achievements in the field of animal cloning open wide prospects for the survival of the humanity. Cloning can be used, for example, to create large herds of highly productive breeds of domestic animals. At the same time, it is necessary to take into account that cloning and selection take opposite directions. Selection increases the biological variety, while mass cloning reduces it and can result in the diminishing of the gene pool and degeneration. Thus, cloning of highly productive domestic animals is undoubtedly important but within the reasonable limits. Cloning of valuable trans-gene animals can quickly and economically provide the humanity with new medicinal preparations contained in the milk of sheep, cows and goats specially reared for this purpose with gene engineering methods. Cloning can also be used to breed prize sporting horses, valuable fur animals, maintenance of rare and vanishing animals in their natural populations. For example, the habitants of Thailand want to clone wild white elephants: in the 1960-s there were 50,000 of these animals, and now only 2,000 of them remained. However, if the modern anthropogenic harming and destruction of their natural environment will not be stopped, the same fate awaits for the clones. It is impossible to solve the problem of flora and fauna preservation only by cloning, while ignoring the initial reasons of their vanishing, although, undoubtedly, cloning with the purpose of main-

taining the populations of the expiring species is a perspective and important direction of animal cloning.

The attitude toward cloning in the world differs, but the moral-ethical point of view that this procedure is socially impermissible in regard to human beings prevails. According to the results of questioning, the majority of the USA citizens consider that cloning as such is morally and legally impermissible, that it will eventually result in problems rather than successes, and that the government should control the technologies related to animal cloning. As to people, Americans are still more unanimous: three quarters of the respondents believe that artificial reproduction conflicts with the Divine will, and one third of them are ready to counteract the experiments on human cloning actively. Only 7% of Americans approve of the hypothetical possibility of having a copy and prolonging their life in this way. However, the members of the scientific community consider that the prohibition of cloning is faulty because it hinders the progress of science. When the President of USA B. Clinton forbade the budgetary financing of research on human cloning and appealed to the researchers who worked with the support of private funds with a request to "resist the temptation to clone oneself", prominent scientists, laureates of the International Academy of Humanism including the Nobel laureates, appealed to him with the Declaration in defence of cloning and inviolability of scientific research.

The possibility of cloning human beings places the humanity before the necessity to change the legal regulation of many issues concerning the medical-biological research. In Europe the basic document which regulates the activity in the field of cloning is the Convention on Human Rights and Biomedicine, accepted by the Parliamentary Assembly of the Council of Europe in November, 1996 (Supplement 5). The Convention was developed before any official statements on successful completion of cloning experiments were made. This explains the absence of direct guidelines related to the regulation of such experiments in this document. The possibility of human cloning is interpreted proceeding from the positions of Article 18 of the Convention. According to part 1 of this article, where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo. Part 2 of Article 18 prohibits the creation of human embryos for research purposes. To specify the norms of the Convention as it applies to the separate fields of biology and medicine, the Steering Committee on Bioethics of the European Council develops additional protocols. An additional protocol unofficially named "The Protocol on the Prohibition of Cloning the Human Beings" was opened to signing of January 15, 1998. This protocol prohibited the cloning of human beings, saying that the instrumentalisation of human beings by creating their genetically identical copies is incompatible with the human dignity, and thus, is practising upon biology and

medicine. The cloning of human beings can cause serious medical, psychological and legal problems for all the individuals engaged in it. Article 1 of the Additional protocol says: "Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited". The article also explains the term "genetically identical human beings" as "human beings sharing the same nuclear gene set". Aiming at the observance of ethical norms, the Additional protocol does not take into account the substantial difference between the concepts of reproductive and therapeutic cloning, and this largely limits its value in the creation of the national regulating bases.

Another international document — the Universal Declaration on the Human Genome and Human Rights, accepted in 1997 the 29th session of the General Conference of UNESCO — also declares the impermissibility of the human beings cloning. Article 11 of the Declaration points out the necessity of international cooperation in identifying the practices of reproductive cloning of human beings and in taking, at national or international level, the measures necessary to prevent such practices.

National laws of the states-members of the European Union, as a rule, do not make distinctions between the concepts of reproductive and therapeutic cloning and prohibit both. The most consistent opponent of cloning in Europe is Germany, which equates the practice of such experiments with the unethical experiments on people carried out under the Nazi regime. The federal law of the Federal Republic of Germany on the protection of embryos (1990) names the creation of an embryo, genetically identical to another living or dead person, a crime. The law of Spain on the procedures promoting the reproduction (1988) also establishes criminal responsibility for the cloning of a human embryo. In Denmark the research in field of cloning is forbidden by the Act on the System of Scientific Committees on Ethics and Biomedical Research Projects Regulation (1992). Similar laws exist in Italy, Netherlands, Sweden, France and Belgium.

The most complicated situation with the prohibition of cloning developed in Great Britain. According to the Human Fertilisation and Embryology Act (1990), cloning is forbidden. It says that the "replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo" is prohibited*. This document, as well as many other European legislative acts, did not make differentiation between the reproductive and therapeutic cloning. The paradox of the situation is that Great Britain actually was the motherland of mammals cloning, and the idea of permission of cloning human beings is very popular in the British scientific community. In 2002 the House of Lords satisfied

* Human Fertilisation and Embryology Act 1990 http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_2.htm#mdiv3

the appeal of the government and abolished the decree which excluded cloning from the jurisdiction of the Human Fertilisation and Embryology Act (1990). In August, 2004 the British state organization HFEA (Human Fertilisation and Embryology Authority)* permitted the cloning of human embryos for medical research. The specialists from the Newcastle university will be the first in the country to carry out this procedure, which causes numerous arguments.

In 2004 therapeutic cloning was allowed by the Scientific Council of Japan.

In the USA the principles of legal regulation of experiments on human beings cloning were formed in the process of opposition between the supporters of prohibition and legalization of the work in this field. The committee on science of the House of Representatives in the Congress of USA voted for complete prohibition of the experiments related to the cloning of human beings on July 30, 1997. It strengthened the decree of the president, prohibiting the provision of federal funds for any research related to the cloning of human beings. On the recommendation of the National Advisory Council on Bioethics of the USA, in 1999 a 5-year moratorium for the state financing of the programs related to the experiments on human embryos, including their cloning, was implemented in USA. The commission recommended to appeal to all firms, practicing doctors, researchers and professional societies, carrying out their activity at the private establishments, financed not from the federal budget, to join to the moratorium declared by federal authorities voluntarily. However, as early as in 2001 the state financing of research in the field of using the human embryos with medical purposes was restored.

In the Russian Federation the work on the cloning of human beings was legislatively halted, as in the majority of the countries in the world. In 1996 the Parliament of Russia accepted the federal law "On the Governmental Control in the Field of Genetic Engineering". In 2002 a special law of the Russian Federation "On Temporal Prohibition of Cloning of Human Beings" was accepted. Article 2 of this law determines cloning as the "creation of a human being genetically identical to another living or dead person, by transferring this person's somatic cell nucleus into a female gamete deprived of the nucleus". The same as in USA, in obedience to the existent legislative acts, cloning is actually not forbidden in Russia but frozen through a moratorium for cloning human beings in the nearest five years.

Concluding the review of the legislative regulation of cloning, we can say that in the world prohibition of cloning the human beings is established in one of three forms: in the form of direct or indirect complete prohibition

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* http://www.hfea.gov.uk/Home

of cloning; prohibition of only the reproductive cloning; and temporal prohibition of cloning.

It is obvious that in future, when the problem of cloning the human beings is fully solved methodically and technically, the humanity will recognise cloning as a method of helping the sterile couples, who wish to have a child of their own. However, it will be necessary to solve some ethical and legal problems before. In the whole world bioethics, its norms and rules become an important and inalienable part of science. It is also obvious that the existent morals, unfortunately, do not provide for those new possibilities and methodologies, which the science brings into the life of society. It is therefore necessary for the public opinion to be based not on the superficial pictures of reproductive technologies, but on the thorough knowledge of this object and on the social responsibility of the researcher. It is also important to create new norms and morals of social existence, taking into account the changes of the surrounding reality.

BIOETHICAL ESTIMATION OF GENE ENGINEERING

Bioethical Aspects of Gene Therapy. Gene therapy is a field of medical knowledge which has developed on the joint of medicine, genetics and molecular biology and occupies all the more important position in modern genetics. It is a gene engineering technology aimed at attaining the therapeutic effect by introducing certain genetic constructions into the human genome. As a result of the achievements made by the molecular genetics, gene and cellular engineering during the last decades a new field of medical knowledge developed, which allows to use functioning genes as medicines.

The treatment of monogenic hereditary diseases and the treatment of acquired illnesses are the two basic directions in the modern gene therapy. In spite of the considerable progress in both directions of gene therapy, the number of unsolved problems does not let this method of treatment extend beyond the limits of experiment. The therapy of monogenic hereditary diseases is at the stage of its origin because the problem of genome correction has not been solved technically. The development of this branch has taken the rout of extra-chromosomal expression of the introduced genetic constructions. Gene therapy of malignant tumours with the cytokine genes, genes which control the apoptosis, and a number of other genetic constructions is also the object of scientific research for the while.

The medical effect of gene therapy can be achieved:

— as a result of correction or replacement of an imperfect gene (this type of therapy is named genetic);

— as a result of extra-chromosomal expression of the introduced therapeutic gene constructions (this type of therapy is named a gene);

— as a result of suppressing the functions of pathological or superactive genes.

Somatic and foetal cells can be the objects of gene therapy. Genetic constructions can be used in the system (injected intravenously or intramuscularly) or locally (introduced directly into the pathologically changed organs or tumours). Local introduction of genetic constructions is used in most presently existing protocols of gene therapy. The viral and non-viral vector systems serve as the transmitters of genetic constructions. The creation of effective and safe vectors in gene therapy is the important constituent of its success. In the opinion of W. F. Andersen (1998), non-viral vectors have certain advantages related to their safety, as well as cheapness and easiness of production. Fully synthetic systems of genes delivery are safer for the recipient than recombined viruses, but the process of effective micro-molecular vector systems development has not been completed yet. It is most probable that when gene therapy is widely introduced in the clinical practice, both viruses and elements of synthetic complexes will be used as vectors for the genetic information delivery. The attempt to use this method in the treatment of adult patients with mucoviscidosis can serve as an example of clinical tests in gene therapy. It is generally known that the reason of this disease is a mutated mucoviscidosis gene located in the 7th chromosome. Using viruses as a vector, scientists undertake attempts of delivering the normal genes directly in the epithelial cells of the tracheobronchial tree of the patients with mucoviscidosis.

The unsolved state of many technical aspects in gene therapy, as well as its nature, cause a number of bioethical contradictions. Serious threats and contradictions involved in gene therapy can be divided into three groups. The first group consists in the danger of interference with the genetic apparatus of subsequent generations, which can cause possible changes of the human nature. Somatic gene therapy involves the second group of dangers related to the interference with the genetic apparatus of the cells of separate organs and tissues with their subsequent malignisation. The third group of dangers is conditioned by the possible negative consequences of the vector systems for the human organism, and if their influence is caused by the use of viral vectors, the danger may concern not only the patient's organism but also the surrounding people.

Thus, one of the main bioethical problems of gene therapy is uncontrolled interference with the genome of future generations with the change

to their heredity. In the somatic gene therapy it is possible to foresee the possibility of out-of-control joining of the vector DNA to the sequences of the genome with the subsequent malignant degeneration of cells. In theory it is also possible that the genetic constructions can reach the gametes and change the genome of future generations.

The basic bioethical questions of gene therapy are:

— when, on what conditions and how widely can it be used;

— how should the medical-genetic consulting be organized;

— how real is the danger of the society "geneticism", i.e. the imposing of certain genetic norms on it;

— whether the practice of "prophylactic" or cosmetic gene therapy is possible in the future;

— whether there is a threat of creating genetically higher and lower classes — bearers of certain genetic signs;

— is the scientific research in field of gene therapy perspective and economically justified.

The fact that in the nearest decades gene therapy will exceed the scopes of biomedical and clinical experiments is fully obvious. Consequently, it is necessary to apply a proper set of legal and ethical regulations to it. Gene therapy is intruding in the most intimate aspects of vital functions, therefore the examination of all scientific research on the part of national ethical committees is justified.

The basic tendency of religious estimation of gene therapy can be illustrated by the model of the Orthodoxy position: "Drawing the people's attention to the moral reasons of ailments, the Church at the same time welcomes the physicians' efforts, directed at the doctoring of hereditary illnesses. However, artificial "improvement" of the human nature and intrusion in the Divine plan concerning the people must not be the purpose of genetic interference. Therefore gene therapy can be carried out only on the consent of the patient or his/her legal representatives and exceptionally on medical indications. Gene therapy of gametes is extremely dangerous, because it can change the genome (the aggregate of hereditary features) in several generations and cause unforeseeable consequences, such as new mutations and destabilization of balance between the human society and the environment".

In the international legal field gene therapy, being one of the objects of gene engineering activity, is a part of the general system of bio-security — a system of measures on providing safe creation, use, import and export of changed live organisms obtained with the help of biotechnology.

The Convention on Human Rights and Biomedicine, accepted by the European Council in 1997 (Sup. 5), drew the public attention to the existence of a serious danger that the human genome can be exposed to inten-

tional change to obtain people or groups with special features and necessary qualities. To avert this threat, any intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants. All kinds of interference, directed at the modification of genetic characteristics, unconnected with illness or indisposition, is forbidden. As presently the gene therapy of somatic cells is at the stage of research, its application is possible only in the cases when it answers the standards of security. Interferences pursuing the purpose to make some alterations in the genome of descendants is forbidden. Therefore, in particular, genetic modifications of spermatozoa or ovules with the aim of impregnation are not allowed. Medical research with the purpose of making genetic alterations in a spermatozoon or ovule unconnected with reproduction is allowed only in artificial conditions on approval of proper bodies engaged in the issues of ethics or management. In connection with the unforeseeable consequences of transferring genetic material to the gametes, most regulating documents at the international level contain the prohibition of such experiments. Forbidding the gene therapy of gametes, the Convention does not prohibit interference with somatic cells, although as was specified above, it also can have undesirable side effects for the gametes.

F. Anderson (1992) formulated three criteria, which became generally accepted for the permission of clinical tests in the field of gene therapy. It is necessary to prove in the experiments on animals, that, firstly, the necessary gene can be transferred to the proper target cells, where it will be functionally active for a long enough time; secondly, being transferred to a new environment, this gene will not lose its expression, i.e. will preserve its efficiency; thirdly, that such a transfer will not cause unfavourable consequences for the organism.

In spite of their seeming simplicity, these conditions can not become a universal rule. It will be necessary to determine for every concrete experiment, what terms of gene efficiency can be considered sufficient, what level of expressivity must be reached, what is the potential risk for the patient and how it correlates with the expected medical effect. This analysis can be executed only within the framework of ethical committees. The participation of independent scientists in their work will enable the committees to estimate the validity and realistic features of the offered clinical tests in a non-preconceived way. For example, there exists a strict checking system of gene therapy procedures, which is named the "System of Permissive Measures for the Procedures of Gene Therapy in the USA". Every protocol of possible gene therapy treatment is first examined by the committee on biological safety of the institution where it will be realised. If the protocol is approved, it is sent to the consulting Council on Recombinant Molecules at the National Institute of

Health for ratification. After the final consideration and approval by national service which supervises the safety of food products and medicinal matters, the protocol must be published in the journal *Human Gene Therapy*. In the majority of European states there also is an exhaust and strict checking system of research in the field of gene therapy.

In Russia scientific research in the field of gene therapy and gene engineering are regulated by the Federal law "On the Governmental Control in the field of Gene Engineering Activity", which has passed the international examination and took effect in 1996. In obedience to this law, the gene-engineering activity must be based on the following principles:

— safety for the citizens (physical persons) and environment;

— harmlessness of the clinical tests of genetic diagnostics and somatic gene therapy methods;

— certification of the products containing the results of gene engineering activity with complete information on the methods of receiving and the properties of this product.

The activities of research workers engaged in gene therapy in Russia is also regulated by the law "On the Transplantation of Organs and/or Tissues". The normative-legal base is constantly perfected, and in 2000 the Russian government passed the Federal law on additions and changes in the legislative document of 1996 "On the Governmental Control in the Field of Gene-engineering Activity". However, even the new normatively-legal base has certain failings, the main of which is the absence of effective control over the fulfilment of the safety conditions and the direct implementation of gene engineering and gene therapeutic procedures.

In Ukraine the normatively-legal base which regulates the gene-engineering activity is also at the stage of development.

Bioethical estimation of the use of genetically modified food stuffs. Genetic modification of products became possible and widely used when considerable successes were achieved by gene engineering in the field of agriculture. The basic problem is that the modified products often cause unforeseeable side effects. We can never be sure that a genetically modified plant used as a food stuff will not suddenly begin to produce new toxins and allergens or increase the level of hidden toxins. It is hard to assert with confidence anything concerning the food value of such plants or their effect upon the environment and wild nature. All these questions are important, but we can not answer them at present. It is difficult to predict how the use of genetically modified products will influence the organism after a while, because to find this out we need to observe several generations of people consuming such food stuffs.

By now several genetically modified sorts of corn, potato, soy, tomatoes and other cultures have bean raised and are already cultivated. The sup-

porters of the application of gene engineering in agriculture are sure: trans-gene food products can cause the users no more harm than ordinary food stuffs. Moreover, some scientists, farmers, public administrators, and (naturally) the producers of trans-gene products are convinced that the humanity will not be able to cope without gene engineering. Basic arguments in behalf on this technology of food stuffs production are as follows:

1. It is expected that during the next 20 years the population of our planet will grow twice, and this will make the problem of providing food more topical. The plants received with the help of gene engineering can provide higher harvests than traditional cultures, they also possess a higher resistance against harmful insects. Thus, the possibility of increasing the productivity is one of the basic arguments in behalf of the trans-gene plants creation.

2. There is a possibility of changing the properties of plants through genetic modification with the aim of increasing the content of nutritive substances and vitamins, and this will result in better balance of nutrition.

3. The genetically modified plants will possess resistance to extreme whether conditions (drought, cold, floods), and this is especially important for the population of the poorest regions of the planet.

4. Genetically modified plants need a smaller quantity of pesticides and herbicides for their growth. For instance, the insertion of a gene of an earthen bacterium *Bacillus thuringiensis* — a natural pesticide — in the corn supplies the plant with its own defence, and there is no need in the additional use of pesticides.

5. Food stuffs containing genetically modified ingredients can become useful for one's health if vaccines against different illnesses are inserted in them.

However, all these reasons are based on the utilitarian approach to the use of genetically modified products. The companies which produce the genetically modified products cover themselves with a myth about the equivalence of food substances. The conception of "food substances equivalence" is used in Europe, North America and everywhere in the world as the basis for the system of regulation. It was created specially to promote the commercialization of the genetically modified food stuffs. For example, this conception makes the basis of the European rules concerning the genetically modified products and ingredients. Equivalence implies that all the products — both ordinary and genetically modified — are identical in all their characteristics, important for the users — safety, food value, and appearance. On the basis of the thesis that genetically modified products are no more dangerous than others, when testing or marking they are classified as equivalent to the ordinary ones and are subjected to simple tests, same as ordinary products, instead of more thorough investigation.

Presently the procedures of testing used in Europe, USA and the whole world consist almost exceptionally in special chemical and biochemical procedures, aimed at making the qualitative assessment of the content of specific nutritive substances, toxins or allergens. These tests focus on the components, which can cause side effects in some genetically modified product. They are based on the known properties of the same substances contained in their unmodified analogues, and also on the descriptions of the genes inserted into the genetically modified plant or animal. Such research can not distinguish every danger hidden in the genetically modified products, because they can not expose unpredicted side effects.

Taking into account that the gene engineering can introduce unknown dangerous properties to the products, every genetically modified product must be exposed to investigation which can expose the widest spectrum of possible dangers. Presently, though, the use of the equivalence conception allows to avoid the necessity of such testing. Only clinical tests can expose all possible dangers and unforeseen side effects which can be hidden in the products of the gene engineering process. The basic and obvious health hazards of genetically modified products are their allergen and toxic properties and the possibility of developing the resistance to antibiotics. We should also mention negative environmental impact of introducing the genetically modified agricultural cultures, in particular on the biological variety.

The issues of creating trans-gene plants and animals require deep philosophical and scientific comprehension because they concern not only the narrow circle of specialists. The question is not only about the modern population but rather about future generations. A certain minimum of the newest genetic knowledge becomes a necessary component part of both special and general education, an index of a person's responsibility for life in the modern world.

Section VIII
ETHICS OF THE BIOMEDICAL RESEARCH

"One should respect a human being in oneself and in others..."

E. Kant

"We can not live without causing death to other creatures, but we can be more or less compassionate. The more compassionate we are to all the animals, the better it is for our soul."

L. M. Tolstoy

BIOETHICS OF THE RESEARCH INVOLVING HUMAN SUBJECTS

Biomedical research (or experiments) involving human subjects concern such major ethical conceptions and principles, as respect for the patient's autonomy and requirement of informed consent, on one hand, and the principle of social justice and social utility — on the other. To clarify the subject of ethical discussions it is expedient to make distinctions between therapeutic and non-therapeutic research.

Therapeutic research includes the actions directed at the alleviation of sufferings, restoration of health or extension of life. "Therapy" in this context is understood widely and includes medical treatment, diagnosing and even taking prophylactic measures, for example vaccination. Naturally, therapeutic research, as any other kind if investigation, helps to obtain new knowledge. However, the patients involved in the research expect and hope to get a therapeutic benefit from the new medicine, vaccine, medical technology or diagnostic procedure — this is the major distinctive sign of these studies. For example, the first patients connected to the hemodialysis apparatus, in fact, were participants of a medical experiment. This medical technology was not used in the clinical practice before and, thus, it was experimental. The obtained information was used by medical professionals for

the improvement of the method and was endowed in scientific knowledge. At the same time this new medical technology was a variant of therapy directed at solving the patient's own medical problems. Its application answered the interests of the patient engaged in the research because the expected results promised to be better in comparison with the results of other kinds of therapy which existed before. It is terminologically right to say that the therapeutic research is synonymous to the clinical tests of new medical preparations and technologies.

Non-therapeutic research (experimental research) includes various scientific actions, the primary purpose of which is to extend the volume of knowledge about physiological, pathological, biochemical or psychological processes in the human organism. Non-therapeutic research provides important information to the biomedical professional, but it is not connected with the treatment of the persons involved in it. It is not expected that the subjects of research will get some medical benefits in its process. In the real practice it is rather difficult to draw a clear demarcation line between the therapeutic and non-therapeutic research. On one hand, therapeutic research is not limited exceptionally by those actions which can bring a benefit to the patient. It is known that science is always directed at getting new knowledge. Moreover, a research project can contain additional procedures, which are not connected with therapy at all. For example, they may include an operation of cannulation or taking samples of blood for research. Such procedures not only have no therapeutic value, but also carry a certain risk. On the other hand, non-therapeutic research can render certain indirect medical benefit, for example in connection with it the involved persons may be subjected to deep medical examination. In spite of the indicated difficulties, the subdividing of research into therapeutic and non-therapeutic provides grounds for the ethical estimations of concrete cases. For instance, there is widespread belief that the level of risk in the therapeutic research, from the ethical point of view, can be higher than the level of risk in the non-therapeutic research.

At present it is considered didactically correct to divide researches into two classes: those, which have the prospect of direct medical benefit and those which don't have such a prospect. In both cases the subjects of every biomedical research project are exposed to certain risks. In this connection the question is: what can be the moral justification of the risk taken by the subjects of biomedical research?

The most widespread grounds for involving people in biomedical research is the conception of utilitarianism. First of all, the clinical tests help to develop and implement new diagnostic and therapeutic technologies. For example, research conducted in the past has enabled the modern doctors to make heart and vascular operations, transplant internal organs, and provide

the prophylaxis of poliomyelitis. Secondly, correctly organized and controlled researches provide the possibility to abstain from ineffective and even harmful treatment procedures. For example, it was proved that bloodletting, widely used in the XIX century medicine, or cooling of the stomach in the patients with the ulcerous illness, applied in the XX century, do not have any therapeutic value, in spite of the fact that these procedures were considered very effective. Utilitarians conclude that clinical tests, considering the mentioned circumstances, are not only morally justified but even morally necessary, because the possible negative consequences for the participants will be greatly outweighed by the medical benefit and prevention of harm for other people in the future.

Often arguments of justice and gratitude are used to justify the involvement of people in biomedical research and sometimes even to defend the point of view that an individual is obliged to be a subject of clinical tests. The supporters of this point of view say that the present generation uses the benefits which became available due to the biomedical researches of the past. The modern achievements of medicine would be impossible without the use of people as the subjects of clinical tests. A conclusion is made from these facts that the modern people are obliged on the basis of justice and gratitude to consent to become subjects of biomedical researches.

An opponent of the argumentation based on justice and gratitude can object, that medical progress, with all its importance, is only a moral purpose. As such it can not be achieved by the violation of individual rights, including the human rights to refuse to participate. Therefore, nobody has an obligation to participate in biomedical researches.

The discussions of the question whether an individual has a duty to become a subject of research or not, reflect the so-called *model of protection from participation in the clinical tests.* This model stresses that the participation in research usually is attended with the risk for the subjects, and points out the importance of their adequate protection. The model of protection is partly based on historical examples, when the subjects were not reliably protected. Recently the positions of the *model of access to participation in research* are growing stronger. This model stresses that the participation in the clinical tests can bring a large benefit to the patients in the absence of effective therapy. For example, the patients' right to participate in long-ranged research in the field of HIV/AIDS and oncology becomes firmly established.

Regardless of the ethical views on the participation in the clinical tests which are realized in the models of defence or access, the receipt of informed consent of the participant or his/her relatives (guardians) is the central question.

In the moral estimation of the research involving human subjects, an important meaning is attached to the conditions on which they are ethically acceptable. After World War II more than 30 documents and ethical codes were developed, in which these terms were identified. The "Nuremberg Code", the "Declaration of Tokyo" and the "Declaration of Helsinki" are the most well known of them (Supplements 15 and 16). The common position of all these codes and declarations concerns the impermissibility of involving human subjects in the biomedical research without their informed consent. The consent of parents or guardians is allowed in some documents.

The grounding of the requirement of informed consent for participation in the clinical test is made in the context of ethics of doctor and patient relationship. The principle of respect for autonomy or the moral value of the principle of individual self-determination are the fundamental deontological arguments. The respect for a human being as a personality requires the defence and development of his/her autonomy. A research in which a human subject is involved without his/her consent violates his/her autonomy and, consequently, is morally unacceptable. The informed consent is the basis of the canon of loyalty between a biomedical researcher and a patient as a subject. It is a deontological counteraction to the attempts to justify the involvement of human subjects in the clinical tests exceptionally on the utilitarian basis. The morally necessary conditions of the human subjects participation in the biomedical experiments are:

1) granting them the information on the nature of tests and the cooperation with the researcher;

2) their desire to take part in the approbation of new methods of treatment or diagnostics.

The experiments made by Nazis at the concentration camps are the most well known historical example of gross and inhuman violation of the principle of informed consent. Later, during the cold war with the USSR, in the United States FBI financed and carried out research with the violation of the principle of informed consent, which involved the subjects belonging to the vulnerable groups of population. The influence of high doses of radiation on the human organism was studied in these research works.

Children, especially the junior age groups, are unable to give their informed consent, thus, any researches with their participation can violate this requirement. The same concerns adult patients which became incompetent because of their grave state, or had never been competent for the reason of mental disorders, serious mental retardation or dementia. The involvement of such a contingent of patients in the biomedical research can be ethically justified if there is a probability of achieving a therapeutic effect. There is a generally accepted opinion that in such cases the parents or guardians can give a legitimate consent on behalf of incompetent individu-

als. The participation of children or incompetent adults in the researches which do not presuppose direct medical benefit for the subject but aim at receiving knowledge which will help future patients are more problematic. Do parents and guardians have a right to give a consent for the participation of incompetent subjects in the non-therapeutic researches?

There is a wide-spread opinion that perspective researches, which do not offer a direct medical benefit to incompetent invalids, nevertheless, can be morally acceptable if they do not exceed the "minimal risk", i.e. the level of risk which is determined in the ordinary circumstances. The supporters of research involving children stress the benefit it renders to all the children as a group of population. The point is that the results of the researches executed on adults not always can be extrapolated to children because of substantial age-dependent anatomical and physiological distinctions. In addition, some diseases are characteristic only of the child age and do not occur in adults. Therefore, the exclusion of children as subjects of biomedical research would considerably impoverish the paediatric medicine and make the children a class of "therapeutic orphans". The same arguments are applicable to the group of mentally sick persons in whom the capacity for decision-making is impaired (temporally, periodically or constantly). Some biomedical researches concerning this contingent of patients must obligatory include incompetent persons to answer the purposes of investigation. Otherwise sufficient understanding of certain mental disorders can never be attained, and their effective therapy can not be developed. For these and other reasons, the development of paediatrics, certain sections of psychiatry, geriatrics and some other fields of medicine can be ethically associated with the involvement of certain groups of incompetent subjects in the biomedical research. Considering the potential advantages of such actions, the moral acceptability of getting the consent from the patients' parents or guardians is generally accepted in certain circumstances. At the same time, the arguments presented by the opponents of the involvement of incompetent patients in biomedical (and especially non-therapeutic) researches are also well known.

Undoubtedly, the vulnerable groups of population must be subjected to additional ethical estimation if they are involved in the biomedical researches. For example, in regard to the child population the following questions are appropriate:

1) Is the clinical research well grounded?

2) How important are the expected results?

3) Would the knowledge obtained by research involving adult subjects be sufficient?

4) Does the research involve only a minimal risk, i.e. the risk which does not exceed the levels expected in ordinary circumstances?

Clinical tests are regulated by international and national documents. The most important of them is the international standard of high-quality clinical practice — the Good Clinical Practice (GCP).

It regulates the planning, organization, conducting, monitoring, audit, analysis, accounting, and documenting of the researches. If the investigators follow the positions of GCP, this guarantees that the clinical tests are well grounded from the ethical and scientific points of view, and are conducted well at all the stages. The standards of GCP provide the validity of information and observance of the patients' rights. Special attention is focused on involving the vulnerable groups of population in the biomedical researches. Besides children and the mentally ill, they include women of the reproductive age, patients in unconscious states, "the mortally sick people and representatives of ethnic minorities" (L. N. Timchenko, V. V. Popov, 2003)

A research on the treatment of syphilis carried out in the USA in 1960-s became a well-known example of racial discrimination. It was discovered later that the group of Afro-Americans ill with syphilis received no therapeutic help, so that the organisers of the study could investigate the natural course of the disease. Meantime, the researchers possessed penicillin, which is a preparation with a well-proved positive effect.

The participation of mortally sick patients in the biomedical researches is usually considered unacceptable if the participation of other groups of population not burdened with such a state is possible. Nevertheless, often the involvement of mortally sick patients in the cohort of examinees is necessary, if the research concerns their disease and its treatment. Moreover, in accordance with the principle of "access to the participation in research", mortally sick patients who express their willingness to participate in clinical tests should not be excluded from the contingent of examinees. During the conduct of researches which involve mortally sick persons bioethical problems are also related to the circumstance that such persons, as a rule, are more subjected to compulsion or unjustified stimulation. Another problem consists in the fact that a research which involves mortally sick patients often entails a risk exceeding the minimal level. An important role in the receipt of informed consent to participate is entrusted to the legal representatives of the patient (relatives or guardians).

Clinical researches involving patients in unconscious states are also closely attended with the practice of getting informed consent. In the real situations these patients' ability to give informed consent is limited, while the time for decision-making concerning their participation in the research is often short, and there is no possibility to contact their official representatives. Ethical norms allow to involve a patient without getting his/her written informed consent only in the cases when their participation in research entails no more than a minimal level of risk and can give a grounded benefit to the

patient. The informed consent in this case is signed by the doctor-researcher and an independent witness (a doctor or nurse not engaged in the research), who confirm that:

— the patient is in a mortal danger and needs the application of an experimental medication;

— it is impossible to get the informed consent from the patient because he is not able to communicate, or it is impossible to get a legally valid consent;

— there is no time to get the consent from the patient's official representative (relative or guardian);

— there is no alternative approved or generally recognised treatment, which would rescue the patient's life with equal or greater probability than the explored method.

The involvement of women in the clinical tests was limited for a long time because of the well-known "thalidomide" tragedy" *. This resulted in negative consequences because of the violation of the sick women's rights: they could not receive timely therapy with more effective preparations in the stage of their clinical testing (the term of a new preparation output to the market makes 4–6 years after the I phase of its testing). The limitations resulted in the situation, in which the efficiency and possibility of using many of the modern medications in women was not studied, although they are prescribed both to men and women. By now the limitations have been abolished, and women are involved in the clinical tests of medicines even at the early phases. The mentioned requirements concern the testing of the biological supplements and medical preparations. The researchers and the ethical committees of the medical institutions are responsible for the observance of the norms in force and testing rules and for the estimation of the possible risk. Clinical researches with female subjects, who can become pregnant at the time when the research is conducted, must be specially controlled by the ethical committees. In some cases ethical committees must make sure that the female subjects who are not pregnant will use contraception while they participate in the research. Moreover, the women must inform the researcher about the planned pregnancy to avoid the unnecessary additional risk.

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* *The thalidomide tragedy*. Thalidomide is a drug that was sold during the late 1950s and 1960s as a sleeping aid and to pregnant women as an antiemetic to combat morning sickness and other symptoms. It was synthesized in West Germany in 1953. It was later (1960–1961) found to be teratogenic in fetal development, most visibly as a cause of amelia or phocomelia, especially if taken during the first 25 to 50 days of pregnancy. Around 15,000 fetuses were damaged by thalidomide, of whom about 12,000 in 46 countries were born with birth defects, with only 8,000 of them surviving past the first year of life. Most of these survivors are still alive, nearly all with disabilities caused by the drug. Thalidomide was banned for its initial intended use as sedative. http://en.wikipedia.org/wiki/Thalidomide

In the Ukrainian legislation the legal and ethical issues of clinical tests are regulated by articles 7 and 8 of the Law of Ukraine "On Medications" (1996); by the "Instruction on the Clinical Testing of Medications and Expert Examination of the Clinical Research Materials", ratified by the Ministry of Health (MH) of Ukraine (order N 281 of 01.11.2000); by the "Model Proposition on Ethical Commissions", ratified by the Ministry of Health of Ukraine (order N 281 of 01.11.2000); by the "Methodological Recommendations on the Clinical Tests of Medications in Ukraine" (MH of Ukraine, 1999). Article 7 of the Law of Ukraine "On Medications", in particular, says that the clinical tests of medications must be carried out after the obligatory estimation of the ethical and morally-legal aspects of the clinical testing program by the ethical commission created and operating at the medical institution which conducts the clinical tests. The proposition on an ethical commission is approved by the MH of Ukraine or a body appointed by it.

Article 8 of the law of Ukraine "On Medications" concerns the protection of a patient's (volunteer's) rights. It says that the clinical tests of medications can be conducted if the patient (volunteer) gives his/her written consent for the participation in the clinical research or the written consent is given by a legal representative of a minor or incompetent patient for his/her participation in the clinical research. A patient (volunteer) or his/her legal representative must receive the information about the essence and possible consequences of the research, about the properties of medication, its expected efficiency, and the risk level. The client which orders the clinical test of a medication is obliged to make an agreement for the insurance of the patients' (volunteers') life and health in the order provided by the current law of the country. The leader of the clinical research is obliged to stop the clinical research or its separate stages if there is a threat to the health or life of the patient (volunteer) caused by the research, and at the will of the patient (volunteer) or his legal representative. The decision on stopping the clinical test of medication or its separate stages is made by the MH of Ukraine or by its plenipotentiary body and by the firm-sponsor of the clinical research if there is a threat to the health or life of the patient (volunteer) caused by the research if the medication proves to be ineffective or if a violation of the ethical norms occurs.

BIOETHICS OF THE RESEARCH INVOLVING ANIMALS

An important component of the humanity development was the transition from the survival strategy to the creation of civilization, the central issue of which was the wellbeing of the mankind. In this context the bio-

medical researches have the task of obtaining knowledge on the physiology and pathology with the aim of developing effective and safe treatment of different diseases. The fact, that the most important scientific discoveries would be impossible without researches involving animals, remains indubitable (Table 1).

Since the beginning of the XX-th century two thirds of the Nobel premiums in the field of medicine were awarded for discoveries and achievements, in the development of which the central role belonged to the researches involving laboratory animals. Without the experiments on animals the progress in the fields of genetics, biochemistry, physiology, pathology, pharmacology, toxicology, hygiene and other branches of the biomedical science would be unthinkable. The modelling of the influence of poisons, traumas, ionising rays, infections and other pathogenic factors on the organism is carried out in the experiments on animals, which simply could not be carried out directly on human subjects.

In the XX-th century the investigations involving animals acquired a gigantic range. Over 10 millions of vertebrate animals are used annually in the world with scientific purposes, for the testing of biologically active substances and in the process of education. This worries both the investigators and the public. It was found that the use of animals in experiments made in the interests of the mankind causes difficult ethical problems. Some of them concern the ethical status of animals, and others — the importance of the investigations.

The first group of problems inquires whether a certain moral status of animals should be acknowledged. If yes, should it be the same as the moral status of human beings? In other words, how grounded are the radical demands for the species equivalence in their moral status, according to which things that are impermissible toward human beings, are equally im-

Table 1. **Examples of scientific achievements obtained as a result of experiments on animals (J. Bryant, L. Baggot la Velle, J. Searle, 2002)**

Time of experiment	Scientific result
XV-th century	The first use of a tight for stopping a hemorrhage
XVI-th century	The description of the blood circulation circles
XVII-th century	The first vaccination
XVIII-th century	The first use of anesthetics The first use of the aseptic technologies

Ending Table 1

Time of experiment	Scientific result
1906	The transplantation of the eye cornea
1907	Blood transfusion
1912	Kidney transplantation
1914	Kidney dialysis
1922	Separation of insulin and treatment of diabetes
1929	Use of penicillin in the treatment of infections
1937	The artificial blood circulation apparatus
	Operations on the open heart
	Artificial heart valves transplantation
	Implantation of artificial heart rhythm stimulators
1937	Use of anticoagulants
1940	Vaccine against whooping cough
1941	Vaccine against diphtheria
1948	Anti-hypertensive medication
1950	Immunosuppressive therapy
1956	Vaccine against poliomyelitis
1967	Heart transplantation
1973	Treatment of leucosis
1979	Anti-asthmatic remedies
1992	Vaccine against meningitis
1995	The discovery of apoptosis *
1998	The first mammal cloning (sheep Dolly)
2000	Dolly has born a lamb (Polly) after natural fertilizing and gestation

* In biology, apoptosis (from the Greek words *apo* = from and *ptosis* = falling, commonly pronounced ap-a-tow'-sis) is one of the main types of programmed cell death (PCD). As such, it is a process of deliberate life relinquishment by an unwanted cell in a multicellular organism. In contrast to necrosis, which is a form of cell death that results from acute cellular injury, apoptosis is carried out in an ordered process that generally confers advantages during an organism's life cycle. For example, the differentiation of human fingers in a developing embryo requires the cells between the fingers to initiate apoptosis so that the fingers can separate. The way the apoptotic process is executed facilitates the safe disposal of cell corpses and fragments. (http://en.wikipedia.org/wiki/Apoptosis)

permissible toward animals, at least toward vertebrates, especially mammals. If the moral status is equivalent, this means that the use of animals (similarly to human beings) in non-clinical researches must be limited, and the requirements of minimal risk and harm must be observed. On the other hand, if the moral status of animals is acknowledged but to a smaller extent than the moral status of people, what are the moral grounds for this attitude? In general, what criteria are taken into account to acknowledge the moral status? In what cases the moral status is complete? We should stress the fact that the supporters of the opinion that people have exclusive and radical prevalence of moral status on the base of certain features — such as their autonomy, morality and intellect — have an objectively weak position, considering the problem of "non-standard" people. The point is that every criterion which serves as the grounds for not acknowledging the moral status of animals (or considering their status to be not complete) will be also a reason for non-acknowledging the moral status in certain categories of people with serious mental disorders, mental retardation or dementia.

It should be pointed out, that the cultural views and the world outlook have a certain role in the discussions concerning the animals having a "complete moral status". In the Western culture a subordinated position of animals is established. Animals are used for food, for the medical purposes, in religious and ritual ceremonies, and even in sport competitions. Moral subordination of animals in comparison to people is rooted in the Judeo-Christian religious traditions with the dominating position of people on Earth. From this perspective the necessity to protect the animals from purposeless harm is grounded, but the human interests are preferred. The transplantation of organs from animals to human beings is permitted. The radical differences between the status of animals and people is grounded on the contradictions between the conceptions of the human origin. The supporters of the divine creation of human beings insist on special relations between God and people, which do not concern the animals. From the evolutionary positions people and other mammals have common ancestors, this is proved by the results of the genetic material comparative analysis.

The Eastern world outlook often gives a higher moral status to the animals than the Western outlook, so the harm done to the animals causes more worry. For instance, the Hinduism includes a doctrine which requires to avoid causing harm to all animal species. There are religious groups which are against killing any living organism: their priests sweep the ground before themselves to remove the insects from their way.

During the last decades changes have occurred in the traditional secular thinking in the West, which had followed the religious attitudes before. The main tendency was the increase of the utilitarian estimation of the extent of good and evil as a result of certain actions toward the animals. Many fol-

lowers of utilitarianism assess pain as evil, and pleasure — as good, irrespective of the kind of organism it concerns. From the position of utilitarianism, an identical type and intensity of pain has identical moral meaningfulness, regardless of who feels it — a human being or an animal. Utilitarians believe, that different attitude toward living creatures depending on their belonging to different species is the same type of discrimination as discrimination on racial, gender and age grounds. The radical point of view consists in unreserved recognition of the complete moral status of the animals: animals, as well as human beings, have rights, including the right to live. Such views are a nourishing environment for extremism, expressed not only in demonstrations with the violations of law and order, but also (especially in Great Britain) in the destructions of laboratories, threats to the address of researchers, and even in physical violence.

The bioethics of experiments involving animals considers not only the problem of their moral status but also the importance of conducting such biomedical researches. The question consists in the extent of necessity to involve an animal in a scientific observation program. How meaningful must the expected results be to justify complete or limited experiments with animals? Is there no alternative in obtaining the necessary information without the use of experimental animals? It is generally recognised that animals can feel pain and keep the memory about it. If it is impossible to do without experiments on animals, it is the experimenter's moral duty to do everything possible to diminish their sufferings.

The basic ethical principles of experimentation with animals are expounded in the "European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes" (Strasburg, 1985). This document became the legal framework of the proper legislative acts and normative positions in Great Britain, the USA, Canada, and a number of other states in Europe and Latin America. The principle of three "Rs" (refinement, reduction, and replacement) became the generally accepted and recognised standard.

The principle of refinement provides the improvement and humanization of animals handling during the preparation and conduction of the experiments. The purpose is to minimise the sufferings of an animal, for example by using anaesthetics while making any painful procedure. If it is necessary to take blood samples for testing frequently, the stress can be diminished by inserting a catheter in a central vein. Sometimes euthanasia is indicated to an animal. It is correct from the ethical point of view to try to improve the life conditions of experimental animals in a vivarium.

The principle of reduction is directed at diminishing the number of animals involved in the experiment. This is possible if the research design is worked out carefully beforehand, and the preliminary results of in-vitro

experiments and computer modelling are taken into account. The optimal minimum of animals necessary for a concrete research is established by the statistical analysis. The variability of individuals in a species, as the basic problem of biological experiments, can be overcome by the use of genetically identical animals. The use of laboratory animals in an experiment eliminates the risk of unplanned losses from infections and diseases. It considerably diminishes the number of animals necessary for receiving the result.

The principle of replacement provides the replacement of experiments on animals by scientific technologies without the use of animals in all cases when this is possible. For example, it is possible to test insulin not with the biological method which involves animals, but with the chromatographic laboratory test. Although complete replacement of animals in the experiments is improbable, the development of alternative models is an attractive idea from the bioethical perspective. The alternative models include:

1. Cultural models (cells, tissues or organs *in-vitro*).

2. Living systems (bacteria, protozoa, embryos of amphibians, and impregnated ovules).

3. Physical and chemical methods of analysis with extrapolation and interpolation in rows of chemical substances with similar properties.

4. The common ethical requirements to the use of vertebrates in the biomedical researches include a number of provisions (A. G. Reznikov, 2003):

5. Experiments on animals are permissible only in the cases when they are aimed at receiving new scientific knowledge, improving the people's or animals' health, preservation of wild-life, are extremely necessary for high-quality teaching and preparation of specialists, testing, forensic medical and criminalistic examination and do not present any threat to people's health.

6. Experiments on animals are justified only when there are sufficient reasons to hope for obtaining such results, which would be substantially instrumental in achieving at least one of the aims listed above. It is impermissible to use animals in the experiments, if these aims can be attained in any other way.

7. It is necessary to avoid literal duplication of a previous research involving animals if it is not done for the aim of experimental verification of the previous results.

8. The choice of animals, their number and methods of research must be carefully grounded before the beginning of experiments and approved by an authorized person or body of bioethical examination.

9. The animals for the experiments must be obtained from a certificated nursery. The use of stray animals conflicts with the principles of bioethics.

10. While experimenting on animals, it is necessary to treat them in a humane way, to avoid distress, pain and causing permanent damage to their

health; their suffering should be alleviated. It is necessary to reduce the number of animals used in experiments, and where possible, use alternative methods, which do not require the involvement of animals.

11. Experiments on animals must be conducted by a skilled researcher which is acquainted with the rules of bioethics and follows them. The use of animals in the educational process is conducted under the supervision of a specially trained teacher.

12. Laboratories, scientific and educational institutions, and organizations, in which experiments on animals are carried out, are subject to attestation by plenipotentiary bodies, including their accordance with the standards of "good laboratory practice" (GLP).

The World Medical Association expressed its opinion on the ethical issues of using animals in the experiments (Supplement 17).

In Ukraine the regulation of experiments on animals in accordance with the principles of bioethics is carried out by the efforts of the Committees and Commissions on bioethics at the Presidiums of the National Academy of Science and the Academy of Medical Science of Ukraine, and by the State Pharmacological Centre of the Ministry of Health of Ukraine. A topical task consists in the determination of responsibility for the violation of the bioethical norms in the field of using the experimental animals. An experimenter and the technical personnel must be morally, disciplinarily and legally responsible for the violation of the established norms. The measure of responsibility depends on the potential or real harm, done to the biological safety of human beings, animals or the environment. Intentional concealment of possible negative consequences of such activity also must be punished.

The information on the conditions of maintenance and use of animals, as well as on the results of experimental work must be open, except for the cases when it can not be divulged in the interests of keeping the state, patent, investigation or commercial secrets. The access to this information must be available, in particular to the public organizations registered in Ukraine, the regulations of which provide the protection of animals and the environment. Constructive co-operation with the public organizations can be useful for the achievement of humane aims, for which the adherents of bioethics strive.

The problem of animals suffering in the course of the biotechnological cycle is close to the bioethical essence of the problem of using animals in the experiments. The modern agro-business develops technologies of breeding the agricultural animals with ultra-fast growth of the body mass in unnaturally small premises. Hormonal preparations and antibiotics are used for this purpose, and their remnants accumulate in the organism of the animals and then get in the organism of human beings.

The agricultural animals have sensations and emotions, they can feel pain, suffering or satisfaction. Their handling must correspond to the humane rules of "five freedoms" (J. Webster):

1. Freedom from thirst, hunger and malnutrition.
2. Freedom from pain, wounds and illness.
3. Freedom from fear and stress.
4. Freedom from discomfort.
5. Freedom to live a normal life.

The bioethical logic of mutual relations between the people and animals in science and biotechnology is determined by the words of Ch. Darwin: "By spreading our sympathy outside the humanity, we will rise ourselves".

Section IX
SEPARATE ETHICAL PROBLEMS OF THE CLINICAL MEDICINE

"The conception of global bioethics will live and change us."

W. Potter

BIOETHICAL PROBLEMS IN TRANSPLANTOLOGY

The formation and development of transplantology began in the 1950s. Murray (transplantation of the kidney), Starzl (transplantation of the liver), Hardy (transplantation of the lungs), and Barnard (transplantation of the heart) were the pioneers of transplantology. With the efforts of these scientists and their followers several centres of transplantology were created, which allowed to rescue or prolong the life of thousands of patients who otherwise would have been doomed to death. The developments of the pharmaceutical industry provided the use of immune suppressors in clinical transplantology, which diminished or levelled the manifestations of the transplant rejection reaction. The progress of transplantology gave rise to a number of questions concerning both the legal and ethical aspects of relations between a donor and recipient. Many of them required legislative settlement, taking into account the cultural features of different countries, and the "mental attitude" of the society to the issues of organs transplantation.

Disputes concern the important social aspects of the medical ethics and their essence consists in the discussion of three basic problems:

1. Grounding of the general moral acceptability of transplanting organs from one person to other.
2. The development of an ethical and legislative base to regulate the procedure of obtaining donor organs.
3. Discussion of the principles of choice of recipient in connection with the limited availability of donor material.

The grounding of the general moral acceptability of organs transplantation from a human being to a human being and from an animal to a human being is closely associated with the religious and world outlook of one or another society. In spite of the existence of a number of psychological, moral and religious questions, the majority of western religious denominations have acknowledged the ethical acceptability of organs transplantation, including the transplantation of heart — the organ, which was traditionally considered the "location of the soul". The use of the non-reproductive cloning technology with the purpose of obtaining the transplantation material allows to solve some bioethical problems but causes other problems instead.

The grounding of the moral acceptability of organs transplantation is closely associated with the development of the criteria for establishing the fact of the potential donor's death. In connection with the appearance of the new criteria of registering death (death of the brain, including its higher departments) certain changes occurred in the very conception of death — the transition from the interpretation of death as an event (moment) to its interpretation as a process, which takes a certain interval of time.

The ethical and legislative base of the procedure of obtaining donor organs is no less contradictory. The problem lies in the field of relationships between an individual and the society. One point of view consists in the idea that a dead person does not need his/her organs any more, so they should automatically become the property of the state to be used in socially permissible purposes, not only for transplantation but also in the spheres of research, education, and therapy. The practice of the so-called presumption of consent is legalized in some countries. It means that if being alive a person did not declare his/her disagreement to the possible posthumous use of his/her organs, after death he/she can become a potential donor, and the consent of his/her relatives will not be required for this. If a person in principle does not agree to be a donor of organs after his/her death, he/she writes a proper statement to a special register of refusals, which is kept by the institution co-ordinating the work of the transplantation centres. Thus, in the absence of an outspoken or implied will of a dying person, his/her organs can be used after his/her death, although the public bodies can prohibit to do so. An important circumstance in the presumption of consent is that the relatives have practically no influence on the fact of the organs being taken. This situation can be justified by the fact that the relatives' opinion can change depending on the extent of their suffering and stress. It is unethical to ask them to make such an important decision in a hurry in the tragic circumstances. This practice exists in a number of Latin-American, Scandinavian and Asiatic countries. However, in the USA, Great Britain, and Germany it is established by law that an individual has various

rights in relation to the state, and these rights include the control over one's own body. In this context the withdrawal of organs is possible only in the case of official consent of the potential donor or his/her substitute representatives in the case of his/her incompetence. This point of view reflects the individualism of the western liberal political philosophy and bases the control of obtaining donor organs on the principles of informed consent, veracity and loyalty to one's obligations.

The consent to donorship must be given voluntarily, any form of compulsion (psychological, physical, or material) is impermissible. If the question concerns the obtaining of such consent from the donor's legal representatives (relatives), this implies the donor's incompetence, in the majority of cases related to his/her critical condition.

The clinical case of Jane Smith can serve as an example, illustrating the ethical aspects of procuring organs for transplantation from persons in a critical state (1992, Pittsburgh, the USA). A doctor informed Jane's relatives that she will die irrespective of the duration of life-supporting therapy. The patient declared that she didn't want her life to be supported artificially if there are no chances for convalescence, so the relatives asked the doctor to stop the artificial lung ventilation and "let" Jane die. The relatives also asked the doctor whether Jane could be a donor of organs. After getting a positive answer, the relatives signed a consent for Jane's organs to be taken. Soon Jane was disconnected from the life supporting apparatuses, lost her consciousness, her heartbeat stopped and the death was registered in 2 minutes. After this a brigade of surgeons began to take her organs for donorship. Such an approach to obtaining organs from dead bodies was named the "Pittsburgh Protocol". More exactly this document is called the "The Tactics of Managing the Terminal Patients, Which are Potential Organ Donors". The advantage of the Pittsburgh Protocol consisted in the possibility of procuring the organs *soon* after the decision is made to stop the life supporting therapy in the patients with critical states. This approach allowed to increase the pool of donors by 20–25% and to improve the quality of transplants, which earlier were considerably damaged as a result of freezing, preservation and protracted storage.

There are two important principles, which regulate the possibility of procuring organs for donorship. Firstly, the patient's death must be registered before his/her organ is procured. Secondly, the care of the still living patient must not be violated "in order to please" the potential recipients.

The authors of the Pittsburgh Protocol adhered to the universal determination of death, but the critics of this document draw attention to the fact, that it allows to establish death too "easily and quickly". For instance, in obedience to the Protocol, the doctors must wait for two minutes after the

breathing and heart activity is halted to register one of the three variants of cardiac disrhythmia — ventricles fibrillation, asystolia or electro-mechanic disassociation, — whereupon death is registered. Are two minutes enough to judge about the *irreversibility* of the functions disturbance? In fact, there is a possibility of their spontaneous restoration. In theory, the physicians during this two-minute period must take active measures of resuscitation of the patient. Can a patient be found dead only because we had decided to discontinue the life supporting therapy?

The supporters of the criteria of higher brain death understand the subject of life and death in a somewhat different way. They consider that the *personality* can be dead, even if the *organism as the whole* remains living. The really important thing is the proceeding existence of the personality, and not the impersonal organism. For example, a baby with anencephaly has a functioning brainstem, but because of the absence of the hemispheres it does not and never will have consciousness. Thus, this child is in a complete and permanent unconscious state. Even if aggressive supporting therapy will be used, he will hardly live more than one or two weeks. Another child has an innate heart-disease — the hypo-genesis of the left ventricle, which with large probability will result in early death. Let us suppose that there is a surgical possibility to transplant the healthy heart of the first child to the second, and this probably will considerably prolong his life-span. The surgeon, though, can not wait until the child with anencephaly will be registered dead. By the time when this child will correspond to the accepted criteria of death, his heart will be badly damaged. The question is whether it will be erroneous for a surgeon to make an operation of heart transplantation from the first child to the second one. If by the word "error" we mean an "illegal action", the answer to the question is clear. According to the existent legislation, such heart transplantation will mean murder. The first child is a living human being, and the surgical operation of heart deletion will become the reason of his death. However, is such an operation rescuing the life of the second child, a severe moral error? If the child with anencephaly is in a complete and permanent unconscious state, will he suffer from the heart ablation? This operation will not cause him pain and suffering and will not deprive him of a normal future. In fact, this child does not differ from a dead body which can be a donor of organs for transplantation. In the USA two thirds of the leading medical experts in the field of ethics consider that the use of organs procured from children with anencephaly for transplantation is moral in essence; more than a half of the specialists spoke out in support of the change of legislation on this issue. The patients with anencephaly, same as the patients in a permanent vegetative state, are in the complete and permanent unconscious state. The main difference between them is that for the first group this state is innate, and

for the second it is acquired. Consequently, the children with anencephaly can be considered dead because of the complete and permanent absence of consciousness, as in some countries the same is considered in regard to the patients in a permanent vegetative state. Can this be a satisfactory solution of the ethical problem?

The most thorny problem of social ethics is the *distribution of organs accessible for transplantation among the enormous number of potential recipients*. For example, presently in the USA about 80,000 persons are included in a waitlist for the operation of organs transplantation. The availability of transplants is constantly limited, and this situation can be changed only in the case of practical revision of the technologies of using artificial organs and animal organs. In the situation of permanent resources deficit decision-making based on the principles of social ethics has the critical importance. In the cases when the mechanisms of making the operations of organs transplantation on an entirely market basis, (i.e. with the use of the patient's and sponsors' financing), the distribution of the limited transplantations resources must be made on the basis of the social benefit and social justice principles.

In the distribution of donor organs on the basis of the social benefit principle the patients which have the greatest chances for a successful operation are chosen as recipients. For instance, in the kidney transplantation the probability of effective organ implantation depends on the degree of the tissues HLA histological compatibility, and the greatest term of the organ endurence in the body occurs in the young males belonging to the white race. The principle of choosing the recipient on the base of the HLA and other objective facts is supported by the majority of specialists in transplantology, but some people, mostly amateurs, object against this principle of choice. Their criticism is conducted from the positions of the criterion of justice and consists in the statement that the selection of recipients only on the base of maximal public benefit, considering the term of the transplant endurance, is a policy which violates the principle of equal human rights. From the point of social justice all the patients must have an equal access to the programs of transplantology, regardless of the genotype which controls the race, gender or type of HLA. A greater equality of rights can be provided by the additional account of such factors as the term of being in a waitlist, extent of urgency of the patient's state, the presence of antibodies to alien tissues after the previous contact with them (which diminishes the probability of a successful operation). The modern principles of recipients selection presuppose an equal account of the principles of social (medical) benefit and social justice in every case.

Taking into account the existent bioethical complications and contradictions, concerning the subject of transplantology, the World Health Organi-

zation developed the basic principles of organs transplantation. The essence of these principles is as follows. Organs and tissues can be taken from a dead body or a living person only on the condition of receiving the consent to it in accordance with the laws. The doctors which register a potential donor's death must not directly participate in procuring organs from him/her, and also must not relate to the potential recipient's treatment, i.e. such doctors must be totally "disinterested" in the transplantation. It is best to procure organs from the corpse material, although transplants can also be taken from living donors (in this case people genetically close to the recipient are preferred). If an organ is taken from a living donor, it is necessary to get his/her written voluntarily consent, and the donor must be informed both about the potential risk for his/her health and about the possible benefit of transplantation for the recipient. The procuring of organs from living minor persons is impermissible. It is necessary to eliminate any commercialization related to the organs transplantation, i.e. payment of fees for the donorship, search of donors with the declared payment for their services or suggestion of donorship for payment. If the doctors have any doubts in regard to the possibility of commercial background of organs transplantation in a concrete situation, they should refuse to participate in this procedure. Donor organs must be equally available for all potential recipients, regardless of their financial possibilities.

Non-admission of commercialization in transplantology is also extremely important in its branches, such as neurotransplantology. This direction of medicine is very perspective in the treatment of such grave organic disturbances of the nervous system, as the Parkinson's, Alzheimer, and Huntington's diseases, epilepsy, schizophrenia, infantile cerebral paralysis, apallic syndrome*, consequences of ischemic stroke and cranio-cerebral traumas. Embryonic (foetal) cerebral tissue is the main donor material in this case. The document which regulates such interferences in Europe is the "Ethical Guidelines for the Use of Human Embryonic or Foetal Tissue for Experimental and Clinical Neurotransplantation and Research" (1994). The most essential positions of this document are as follows. Embryonic tissue for transplantation or research may be obtained from dead embryos or foetuses, their death resulting from spontaneous or legal medical abortion. In the last case the decision on the abortion is made by the woman without any interference or pressure on the part of the doctors — transplantologists.

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* (This is an older, non-specific term.) The behaviour that accompanies diffuse bilateral degeneration of the cerebral cortex that sometimes follows anoxic brain injury. It describes patients with absent cortical function but with relatively intact brain stem function. http://www.northeastcenter.com/brain_injury_glossary_apallic_syndrome.htm

The pregnant woman must be informed about the possibility of using the embryonic tissues for medical aims, and it is necessary to obtain her voluntarily written consent to such a procedure. The woman must not know to whom the embryonic tissue can be transplanted, she must not get any fee for the donorship. Thus, the observance of these principles excludes the use of transplants from the so-called contractual (commercial) abortions.

Transplantation of the stem cells is another direction of transplantology, which is intensively developed during the last decades. Cellular transplantation includes primarily the use of alogenic embryonic stem cells, obtained from the abortion material or from the embryos not used for endometrial implantation after the extracorporeal impregnation. It is also possible to use autologic and alogenic stem cells of the umbilical cord, hemopoetic stem cells and partly determined cells of the postnatal organism.

In Ukraine for the present no official ethical and legal acts on the procuring and use of embryonic organs and tissues were adopted. There also are no normative documents on the transplantation of artificially created organs or stem cells. There are no instructions which regulate the criteria of the stem cells quality and the responsibility of the medical workers for the possible negative consequences of cellular therapy. The observance of the principle of obtaining the voluntarily informed consent from the donor of embryonic cells is very important. Considering that in the majority of cases such a donor is a woman who had made a decision to terminate her pregnancy, the observance of the principle of presumed consent of the abortive material donor is offered. This approach is based on the fact that by the voluntary refusal to bear the pregnancy the woman looses her right for the abortive material, which is not subject to burial but is simply destroyed. The presumption of consent of the abortive material donor must be applied only in the gestational term of the artificial termination of pregnancy established by law.

The transplantation of stem cells is attended with a number of certain risks for the recipient. They include the problem of histological compatibility, the possibility of cells and cultural medium infection with pathogenic micro-organisms, the possibility of tumour growth after the transplantation of stem cells, the possible unknown influence of these cells on the recipient's reproductive potential. It is obvious that before the wide introduction of cellular transplantology in the clinical practice these issues must be solved in the experimental researches.

One of the important ethical and legal moments affecting the transplantology is the observance of the most strict medical secret in regard to the source of the donor organs. It implies that neither the donor's family, nor the family of the recipient must receive the information about each other in order to avoid the appearance of unforeseeable legal and moral conflicts.

BIOETHICAL PROBLEMS OF THE HIV-INFECTION AND AIDS

The epidemic spreading of the HIV-infection became a source of ethical problems, which concern not only the personality and interpersonal relations, but also all the world community. The problem of ethical relationships became topical from the very beginning of the HIV-infection epidemic and initially was connected with the concept of "stigma" (label, stamp). Stigmatization means the change of interpersonal relations and a person's attitude toward him/herself as a carrier of a certain sign, for example HIV infection.

Bioethics, while studying the human personality in the new life conditions, which have developed owing to the biomedical sciences progress, is all the more widely used in solving the problems related to the epidemic of HIV-infection and AIDS. The bioethical problems of HIV infection and AIDS involve the issues of stigmatisation, discrimination, providing the medical examinations and clinical tests, confidentiality of the medical information, rendering medical help in the terminal stage of disease and other issues.

The Clinical Ethics. The important problem of the clinical ethics related to HIV infection is the voluntarily testing and consulting of patients on the basis of their informed consent. In this case the informed consent means a person's voluntarily consent to undergo a medical test for HIV infection after getting the information about the aims and the possible results of the testing. The voluntarily consent is a principally important moment in the process of the patient's decision-making. This means that the medical workers must not deceive or threaten the patient to force him/her to make a certain decision.

The question concerning the confidentiality of information about a person's HIV-status is, on one hand, ethical, and on the other it is regulated by law. In obedience to the Law of Ukraine "On the Prevention of the Acquired Immunodeficiency Syndrome and Social Protection of the Population", the information on the results of testing for HIV is confidential, and its disclosure entails criminal responsibility.

The refusal to provide medical care to HIV-infected patients is the problem of both clinical and social ethics: it is a result of insufficient knowledge of the medical workers and the low level of public consciousness.

The development and clinical testing of new medicinal preparations and vaccines for the treatment of the HIV infection is an important and humane task. However, its successful solving is impossible without strict observance of the ethical norms: the respect to every human being as a personali-

ty, charity, mercy and justice. The principle of charity and mercy means that the care for the benefit of a concrete patient must be the basic reason of every clinical test. Justice presupposes the principle of equal opportunities for the patients in the availability of medical care and distribution of medical services. It is important to get a patient's informed consent for carrying out clinical tests. The organiser of the clinical tests is responsible for informing the patients and for the adequacy and veracity of the provided information, and this responsibility can not be readdressed to any third persons. A patient has a right to refuse to participate in the clinical test. In the case of a patient's incompetence the voluntarily informed consent must be received from his/her guardian in accordance with the law.

In the analysis of the behavioural or biological information related to the HIV infection it is necessary to observe the highest level of ethical norms. The failure to observe the ethical norms can turn the HIV-infected people into derelicts and result in the violation of their basic rights. It is necessary to take into account that psychological, social, physical or economic harm can be done to the participants of such researches (even if all precautionary measures are taken). The rules and the guidelines of collecting the data must include the detailed descriptions of protection measures for the participants of such researches. Scientific and financings organizations require high-quality control of all researches, in particular of those which are conducted in the developing countries. Although many procedures of collecting information related to the programs of AIDS prophylaxis and treatment and the improvement of the patients' conditions can not be considered research, but the basic principles of research activities should be used in the course of this work, when it concerns the information about concrete people.

The possibility to provide the prophylaxis of HIV transmission from a mother to her child dictates the necessity of skilled consulting of HIV infected women on the problems of reproductive choice. Global bioethical problems of family planning, artificial termination of pregnancy, artificial congestion and other issues are refracted in the context of the HIV infection.

The AIDS has a progressive course, and there is a necessity of rendering specialized palliative help in the terminal stage of the disease. In the cases when it is impossible to cope with the pain or other symptoms of the disease, which make the patient suffer, the question of passive euthanasia arises — helping the patient in terminating his/her life. However this problem is far from being simple and clear, because the use of new schemes of treatment can have substantial influence on the quality and duration of the patients' life.

Social ethics. The global epidemic of HIV infection is a factor which disturbs the socio-economic development and stability, affects both nations and states on the whole and every separate person in particular. From the

UN data, 90% of the HIV-infected people live in the developing countries, 75% of them — in the African countries, located south of Sahara. The problem of HIV-infection in this region is considered by the world community as an extraordinary situation, which threatens the development, the political stability, and the food safety. The rate of the epidemic of HIV-infection development in the East European countries demonstrates the potential possibility of rapid spreading of the epidemic in the whole world. At the same time in some countries of Western Europe and in the USA real progress in the inhibition of the epidemic was attained by the mobilization of the state and public resources. Therefore on June 27, 2001 the "Declaration of Commitment on HIV/AIDS" was passed by the special session of the UN General Assembly, convoked on the initiative of Ukraine. It suggested to support at the global level more active measures and co-ordination of all the concerned organizations of the UN system, and to encourage more active co-operation and development of new partners connections between the state and public organizations of different countries. The Declaration also called to strengthen the international and regional cooperation related to the transfers of modern technologies applied with the account of local features, for the prophylaxis of HIV infection, treatment and care of the patients.

The epidemic of HIV infection set a task before the society to develop a system of primary prevention, especially among the risk groups, and to a great extent changed the social attitude toward the sexual minorities and the users of injection narcotic drugs. However, the measures of primary prophylaxis of the HIV infection often contradict the existent norms of public morals. This explains the difficulty of creating an effective preventive system, the basic task of which is to change the models of behaviour of concrete individuals. The primary prevention of the HIV infection can be addressed both to the society on the whole, and to certain groups of population. The success of the primary prevention is conditioned by the implementation of the following social conditions:

1. Awareness of the danger of the HIV infection epidemic spreading at the governmental level.
2. Development of the national strategy of primary prevention, adequate to the threat of the HIV infection spreading.
3. Development and financing of preventive programs against HIV transmission from mother to child.
4. Financing of the patients treatment programs.
5. Introduction of the programs of diminishing the harm done by the injection use of drugs.

The ethical norms existing in the society in a number of cases cause stigmatisation in regard to the HIV infected people. The factors which cause

the patients stigmatisation include the picture of HIV infection as an incurable illness associated with behaviours blamed in the society: drugs abuse, homosexual connections or sex-business. The stigma is displayed in various ways and, as a rule, its manifestations are closely interlinked with each other. The term "cultural stigma" means public norms and attitudes, according to which people belonging to certain groups are considered less moral than others and are attributed to the marginal strata of the society. The cultural stigma often originates from negative, frightening information in the mass media or negative social advertising. The term "institutional stigma" designs a discriminatory attitude toward the HIV infected people on the part of public, health, and church authorities. Personal and interpersonal stigma, which is a direct consequence of the cultural and institutional stigma, is the people's personal prejudice, expressed in the form of fear, contempt or rejection. All these forms of the HIV infected people stigmatisation are external, because they reflect the attitude of the society toward a limited group of patients. The internal stigma reflects the interpersonal relations and experiences within the group to which the patients belong. It can show up in the feeling one's inferiority, in the inability to establish normal social relations, in the fear of discrimination on the part of the society and other people, or in a feeling of helplessness and absence of interest toward life.

The development of the state social policy and the assessment of the effectiveness of preventive programs are based on the principle of partnership with the public organizations. The involvement of the population, which belongs to the risk groups, helps to go deeper in the essence of the problem, to mobilize the resources for the protection of the human rights, exclusion of discrimination, and the observance of basic ethical norms.

The Legal Bases of HIV infection/AIDS Prevention in Ukraine. The global pandemic of the HIV infection, among the centres of which are Ukraine and other new independent states, has caused a great number of medical and socio-economic problems which are difficult to solve. They entail serious consequences and require special measures directed at the protection of every individual's personal rights, as well as the interests of the society as a whole.

According to Article 3 of the Constitution of Ukraine, a human being, his or her life and health, honor and dignity, inviolability and security are recognized as the highest social value in Ukraine; the realization of the human rights is guaranteed by articles 21, 22, 24, 49 and others. Article 49 of the Constitution makes the state responsible for the provision of the sanitary-epidemic wellbeing in the country. Ukraine was the first among the countries of the CIS to pass the Law "On the Prevention of AIDS and

Social Protection of the Population" in 1991. During the time which has passed since the day this Law was adopted, the epidemic situation in Ukraine has changed sharply. The HIV infection spreads quickly through this country. Some of the Law provisions began to conflict with the international practice, good sense and obligation of Ukraine before the European Council to make its legislation more humane. Therefore, on March, 3, 1998 a new version of this Law was adopted. Its preamble stresses its accordance with the norms of international law and recommendations of the World Health Organization. AIDS is marked as a phenomenon which creates a threat to the personal, public and state security. In the generals of the Law the HIV infection is determined as a disease caused by the human immunodeficiency virus. The category of HIV infected people includes both the persons with no clinical symptoms of illness (carriers of HIV) and the patients ill with AIDS. The acquired immunodeficiency syndrome is the final stage of the HIV infection. The Ministry of Health of Ukraine is the specially authorized central body of executive power, responsible for the management and interdepartmental co-ordination in the field of fight against AIDS.

The first National AIDS prevention program was approved in 1992, when the National Presidential committee on AIDS prevention was created in Ukraine. The amendments to the Criminal code abolishing the criminal responsibility for homosexuality, accepted the same year, became the initial stage of the legislation humanizing.

The programs of HIV infection prevention among the users of injection narcotic drugs began to be carried out in Ukraine since 1996. In 1998, after the adoption of the new version of the Law "On the Prevention of AIDS and Social Protection of the Population", the legislative aspects of HIV infection were modified in accordance with the norms of international law. In the legislative acts an accent was made on the absolute observance of human rights. On November 1, 2000 the president of Ukraine signed the Decree "On the Urgent Measures for the Prevention of HIV infection/ AIDS Spreading", in accordance to which a Governmental commission was created for the operative solving of problems related to the measures on protecting the population from the HIV infection/AIDS. The Cabinet of Ukraine had to prepare and confirm the Program of HIV infection/AIDS Prevention in Ukraine in 2001–2003. In obedience to Order N 120 of the Ministry of Health of Ukraine of 25.05.2000, preventive measures against the transmission of HIV from mother to child began to be carried out in all the regions of Ukraine. By the decree of the President of Ukraine, the 2002 in our country was declared to be the Year of Struggle Against AIDS.

In accordance with the Law "On the Acquired Immunodeficiency Syndrome Prevention and Social Protection of the Population", the state undertook a number of obligations on providing tests for HIV infection. The

citizens of Ukraine can undergo the blood testing for HIV only voluntarily (except for donors), if they wish — anonymously, and necessarily free of charge.

According to the old version of the Law, medical tests for HIV infection were obligatory not only for the donors but also for the users of injection drugs and the women in sex-business. The experience showed that the implementation of the provisions of this Law as to the testing of the injection drugs users for HIV every six months (considering their tendency to use dirty syringes), does not help to prevent AIDS among this group of population. The concepts of "sex-business" and "prostitution" did not find a reflection in the legal field of Ukraine. According to the new version of the Law, only the donors of biological preparations (human blood, sperm, cells, tissues, organs, etc.) are obligatory tested for HIV. All the other categories of population, including the prisoners, are tested voluntarily. Moreover, it is not allowed to make a test for AIDS without informing the patient about this. A doctor is obliged to consult the patient both before and after the testing for HIV. A doctor must also comment on the positive or negative result of the investigation.

Blood (or its components) transfusion and the use of other biological liquids, cells or organs with medical purposes are allowed only after the obligatory laboratory testing of the donor's blood for HIV infection. However, the realities of medical practice show that it is not always possible to provide this verification in urgent cases. In such cases the law allows to transfuse the blood tested for the HIV infection with an express method on the patient-recipient's or his/her legal representative's consent. The patient or his/her legal representative must be warned about the possible risk of HIV infection. The fact of such blood transfusion and the consent should be registered in the patient's medical document, and the sample of blood should be quickly sent for proper testing through the determination of antibodies with standard methods. The right to carry out the medical tests for the HIV infection is given to the laboratories, accredited in the order established by the Cabinet of Ukraine.

In obedience to the Law, the registration of the HIV-infected citizens and patients with AIDS, as well as the medical help rendered to them, must be carried out with the observance of the principles of confidentiality and respect to their personal rights and freedoms, which are provided by the laws and international agreements of Ukraine. Medical care of the HIV infected and patients with AIDS is carried out on the commons grounds. In the case of receiving the information about the HIV infection, the citizens are warned about the necessity of taking preventive measures with the purpose of prophylaxis of spreading the HIV infection, and about the criminal responsibility for intentional exposing others to the risk of infection or

infecting other people. The HIV infected person is obliged to confirm the fact of receiving the mentioned information and warning in the written form. He/she is also obliged to take preventive measures against spreading the HIV infection and to notify the persons who had sexual contacts with him/her before the discovery of the fact of infection, about possibility of their infection.

The HIV infected and ill with AIDS citizens of Ukraine enjoy all the rights and freedoms provided by the Constitution and Laws of Ukraine. In addition to the common rights and freedoms, they also have a right to:

— to get the indemnity for the harm done by the disclosure of information on the fact of their infection with the human immunodeficiency virus;

— to be freely provided with medicines, necessary for the treatment of any disease they have, facilities of personal prophylaxis, and also the social and psychological support;

— to travel to the place of treatment and back home at the expense of the medical institution, which had referred them for treatment;

— to use an isolated dwelling room.

Unfortunately, the proclaimed rights of the HIV infected people are not always realized in the real life because of the socio-economic reasons.

Parents of HIV infected children or children ill with AIDS, as well as the substitute parents, have the rights to:

— stay at the inpatient medical institutions together with their children under the age of 14 years with the release from work and payment of an allowance for temporal disability in connection with the care of a sick child;

— if one of the parents has to leave his/her employment in connection with the care of a sick child under the age of 16 years, they have a right to preserve the continuous length of service to get the extra charge of allowance for temporal disability on the condition of returning to work when the child is 16 years old.

HIV infected children under the age of 16 years receive a monthly state allowance, the sum of which is established by the Cabinet of Ukraine.

The law determines that the infection of the medical and pharmaceutical workers with HIV during the execution of their professional duties is a professional disease. In this connection an obligatory insurance of this category of workers for the case of being infected with HIV in the course of their professional activities is provided at the expense of the owner of the health service where they work.

Medical workers who were infected in the course of their professional activities have a right to: get annual free sanatorium-resort treatment; get annual vacation 56 calendars days long in summer or in any other period comfortable for them; primary improvement of their housings conditions is the order established by the law of Ukraine.

A failure to fulfil the provisions of the Law by the HIV infected people and by the medical workers is subject to criminal and administrative responsibility. Article 130 of the Criminal Code (CC) of Ukraine provides criminal punishment for intentional exposing another person to the danger of human immunodeficiency virus infection; for the infecting of another person with this virus by a person who knew that he/she is a carrier of this virus. At the same time the criminal law provides the punishment of a medical, pharmaceutical or another worker for improper execution of his/her professional duties, which entailed infecting of one or several persons with HIV (article 131 of the CC of Ukraine). The disclosure of the information concerning the results of somebody's testing for HIV by an official person of a medical institution or a medical worker is criminally punishable (article 132 of the CC of Ukraine). In addition, the action of article 139 of the CC on the "Refusal of a medical worker to render help to a patient" concerns also a medical worker's refusal to help a HIV infected person.

In a number of countries — Germany, Switzerland, Czekhia, Slovakia, Austria, Belgium, France, and Netherlands — courts had passed judgements in regard to the carriers of HIV, who had infected or threatened to infect other people. The laws of these countries contain no specific provisions on the punishment for spreading HIV. For example, in the legislation of Austria, Switzerland, Czekhia, or Slovakia there are only general provisions concerning the punishment for exposing other people to danger by their infection with communicable disease.

In the majority of cases on the infection during sexual intercourse it is very difficult or impossible to prove that the victim's infection had occurred this way, because the source of infection could be different. In fact, the nature of this illness makes the proof very difficult. The latent period between the infection and the appearance of antibodies in the blood on one hand, and the latent period between the infection and the appearance of AIDS symptoms on the other, makes it very hard to establish which sexual contact caused the infection. That is why the courts often base their judgements not on the action but rather on the attempt of its committing.

The transmission of HIV can also entail civil responsibility. The infected partner can start a civil case against his/her spouse on the compensation for the property, somatic and moral damage.

There is a wide-spread opinion that presently every person consciously takes a risk by having sexual intercourse without preventive measures. The state can not protect each person from his/her own carelessness or even free choice.

ECOLOGICAL ETHICS IN THE SYSTEM OF GLOBAL BIOETHICS

In the XX-th century the humanity was confronted with the catastrophic consequences of a global ecological crisis. The physical survival, the continuation of the human genus and the development of the civilization depends on this principally new phenomenon. The critical phase of relations and contradictions between the society and nature is conditioned by a giant growth of the natural resources consumption, the change of landscapes, creation of new anthropogenic environment and the violation of the dynamic balance in the biosphere at different levels of its organization. The contemporary ecological crisis caused by scientific and technical progress consists in the striving of the people to subordinate the nature, leaving no place to the protection of the environment, and this presents a qualitatively new threat to the mankind. Mass disafforestation, soil erosion, elimination of separate species of animals and plants, destruction of the ozone stratum, global rise in the temperature caused by the development of the hotbed effect — all this can lead to unforeseeable natural cataclysms and climatic changes, which are related to serious long-term problems for the subsequent generations. The global nature of the ecological disasters, their spreading over all the planet is the substantial negative side of the contemporary situation. A special danger for the mankind and the environment is caused by the so-called risk technologies: atomic energy, chemical industry and new biotechnologies. This danger is connected with the risk of accidents in the process of production and transporting of the materials, the problem of waist utilization, application of nuclear and biological weapons, pollution of the environment with high-toxic products of enterprises, damage of the human genome and undermining the people's health. The contemporary civilization irresponsibly shifts the removing of the major ecological problems to the subsequent generations. The solution of the problem of the global ecological crisis is related to the combination of the economic development aims with the maintenance of ecological balance and resource stability on the planet. The philosophical and world outlook aspects of the global ecological crisis are considered as the issues of the mankind survival.

The psychosocial tasks in the context of the discussed problem consist in the necessity to render psychological and social support to the population. The problem of dynamic balance and adaptive-homoeostatic conduct of people in the "mankind — nature" system has a decisive significance for the present and future of the humanity. The absence of due attention to this problem causes the development of the human beings biological maladjust-

ment to the dwelling environment created by them. The medical aspects of the global ecological crisis are related to the prevention and therapy of the pathological states and diseases caused by the ecological factors. The ecological pathological states (pre-morbid, third states, pre-clinical forms, larval or latent periods) develop latently because of the cumulative impact of small doses of ecological factors changed by the human activity, and are manifested in general-pathological changes at the molecular, sub-cellular and cellular levels. The initial symptoms of ecological pathology can be conditioned by the development of secondary or metabolic immune-suppression, resulting in the induction of chronic and recurrent infectious or inflammatory diseases. Psychosomatic disorders, allergic reactions, or gastro-enteric dysfunctions are typical for this kind of pathology. Unlike the ecological pathology (latent states), the ecological diseases (nosological forms) are specific illnesses with certain symptoms, pathogenesis and clinical course, which develop because of the impact of certain chemical or physical stimuli.

The global ecological crisis has created a number of problems, the solving of which became the primary concern of the humanity in the XXI-st century. To the question, whether the prognoses concerning the catastrophic development of the conflict between the humanity and its environment are real, we must undoubtedly give a positive answer. The strategy of actions was clearly formulated by the UN: "We must spare no effort to free all of humanity, and above all our children and grandchildren, from the threat of living on a planet irredeemably spoilt by human activities, and whose resources would no longer be sufficient for their needs" (the United Nations Millennium Declaration, adopted by the General Assembly on September 8, 2002)*. The ecological problems must be solved today not at the level of separate states but by adopting international ecological laws based on general responsibility of all the countries — members of the world community.

From the philosophical point of view it is necessary to attribute the global ecological crisis to the objective results of the "mankind — nature" system evolution. In the principally new terms of the mankind existence people are facing the necessity of adopting a new ethics of careful and responsible attitude toward nature. The possibility to counteract the global ecological crisis exists on principle, but only the future will show whether the people will be able to use their last chance of survival as biological species.

The technologies created by people, some economic and political structures, and the people's negative traits, such as short-sightedness, avidity and foolishness, were instrumental in the creation of the global ecological crisis situation. From the world outlook perspective all these factors can be considered as the system properties of the biosphere in the process of its

* http://www.un.org/millennium/declaration/ares552e.htm

evolution. They result in the entropy and chaos growth and in the simplification of the "humanity — nature" system, i.e. the induction of the processes of its dying. An attempt to comprehend and solve the problems of the global ecological crisis is an important section of bioethics, one of the tasks of which is the study and characterising of the morality of human activities in the biomedical aspect.

The modern society is characterized by a deep spiritual crisis, devaluation of the moral values, consumer nature of the civilization, lack of global ideas, technocratic thinking, pragmatism and cynicism. Bioethics in the wide understanding of this word became an answer to the negative consequences of the introduction of the newest biomedical technologies and the manifestations of the global ecological crisis in the conditions of the ideological insolvency of the society. In this connection it seams appropriate to include in the everyday life terminology the concept of "global bioethics" (that is, bioethics in the wide understanding). Biomedical and ecological ethics became its constituents, which developed as a result of the realized aspiring of the humanity to survival by the maintenance of the biosphere on the basis of uniting the modern achievements of science and practice with morality and spirituality, and also the protection of the natural control mechanisms of the biosphere.

Retrospective estimation of the history of bioethics shows that in the 1970-s it concentrated its attention on the defence of human rights, in the 1980-s it was directed at the problem of improving the quality of life, and in the 1990-s it acquired the nature of global bioethics. Unfortunately, in spite of the awareness of the threat of a global ecocatastrophe, the active work of bioethical institutions, governments, parliaments, governmental and non-governmental organisations, doctors, lawyers, teachers, environmentalists, church and wide public, the negative tendencies of the biosphere degradation was not overcome by the end of the XX century, and the humanity entered into the XXI century with an increasing load of unsolved problems.

The modern development of the science of hygiene, the "ecological comprehension" of the humanity vital space, and its relationships with the environment are impossible without taking into account the humanistic orientations, including their bioethical aspect. It is the bioethical constituent of hygiene and medical ecology, which should form the social space for the integration of the fundamental and applied sciences with the purpose of creating a highly civilized noosphere (The noosphere can be seen as the "sphere of human thought". In the original theory of V. Vernadsky, the noosphere is the third in a succession of phases of development of the Earth, after the geosphere (inanimate matter) and the biosphere (biological life). Just as the emergence of life fundamentally transformed the geo-

sphere, the emergence of human cognition fundamentally transforms the biosphere. Vernadsky's noosphere is not something that is just now coming into being, or will emerge in the future; it arrived with the birth of the first cognitive human being, and is manifested throughout the geosphere and biosphere in the form of human intervention, which principally takes the form of physical economic development of the planet. — *the translator's note*)*. Unfortunately, in the society the development of which is based on the priority of economic, instead of social indexes, the necessity of active protection of the environment is quite often ignored. This results in the increase of morbidity of the population, including the ecologically based pathology.

The world outlook which accompanies the ecological activity, can be relatively divided into two directions. One of them is based on the technocratic priorities of the society and aims at forming the ecologic-economical co-operations. In our time of swift development of intellect many people consider that the ecological knowledge must be based on the technical and economical world outlook. However, the ecological researches show that the activities based on the supremacy of technocratic world view principles and the priority of economic relations already have generated the ecological crisis, which shows up in the gradual destruction of both the environment and the mankind. The analysis of the ecological phenomena, the primary cause of which are anthropogenic activities, shows the necessity to consider the nature as a morally-world outlook value, and gives grounds to bring it into the sphere of moral relations. In this connection, 30 years ago another world outlook has developed in the philosophy of ecology — the ecological bioethics, which gradually becomes the main regulator of co-operation between the people, society and environment. The ecological bioethics is grounded on the humanistic apperception of the world, which is formed on the principles of life ethics (or bioethics) based on the nature-centrism. This direction positively transforms both the ecologic-economical world outlook and the world view orientations of the technical development methodologies within the framework of bioethical principles and categories. In the light of the ecological bioethics people realise the intention to create an ecologically based model of interdependence between different living forms. Ecological bioethics establishes the value and rights for all the creatures and the nature on the whole, and considers human beings as equal members of the ecologic system. It includes the ethics of humane attitude toward all the living creatures, the ethics of people's co-operation with the biosphere and noosphere. The faith in the creative possibilities of human beings becomes the basis of the ecological bioethics world outlook. Its leading principles are the awe toward life, respect to the free development of every creature on the planet and to everything created by nature, beneficent attitude, justice,

* http://en.wikipedia.org/wiki/Noosphere

collaboration, moral responsibility, solidarity, collective nature, competence, protection, and loyalty.

An example of this approach is the legislative base, which exists in the developed countries concerning the stock-raising, which induces the producers to adhere to minimal standards of providing a certain level of well-being for animals. The rules of keeping animals, which provide at least a minimal level of their wellbeing, were established by the international and European trade agreements, and are controlled by the producers and users of the stock-raising products.

The modern state of the system of using natural resources deserves a separate ecological estimation. During all the period of the agriculture existence the humanity has realized only two stages of agricultural use of natural resources — extensive agriculture (which had lasted for millenniums) and intensive agriculture (which lasts for decades). At the beginning of the third millennium the humanity must start the ecologically adaptive development of the agro-industrial complex. At the Intergovernmental United Nations Conference on Environment and Development (Brazil, 1992) the global strategy of stable development of the civilization in the XXI-st century was discussed. The necessity to overcome the negative consequences of the agriculture intensification was at the base of the new strategy of adaptive intensification. Its realization is the inalienable condition of survival and steady development of the civilization on Earth. The long-term strategy of plants protection, related to the total elimination of harmful kinds, inflicted enormous harm to the environment. The modern ecology allows a broader estimation of the role of different groups of animals and micro-organisms in the agro-biocenoses, on principle eliminating their classification into harmful and useful kinds. The regulation of the number of harmful organisms in the agro-biocenoses is based on the concept that in the natural biocenoses species are able to respond with compensatory reactions to the changes in the number of their own population or the population of another species. Such links of the trophic chains, as predator-victim, parasite-host, phytophague-plant, act as the regulator mechanisms. Most closely these principles will be realized in the integrated systems of plants protection, which consist of the monitoring of the phyto-sanitary state, selection of dominant phytophagues, the biotic potential, a specific composition and number of predators, complex of prophylactic and destructive measures with the use of biological, agro-technical and other non-chemical facilities and methods. The regulation of the adaptive potential must take into account such major characteristics of the agro-ecosystem as biologic diversity of species and sorts, and also micro- and macro-structure features of its biotypes.

People have also realised the necessity to organise agriculture on the basis of the laws of the natural landscapes and ecosystems functioning. The

agrarian activity on the landscape basis can provide economically expedient and ecologically safe use of natural and anthropogenic power resources. The principal difference consists in the necessity to determine the structure territorial units for the system analysis and the quantitative estimation of the bio-power processes which occur in them. The development of the systems of agriculture on the landscape basis provides for the priority of landscape morphogenic structure of the territory over its administrative and economic borders.

The contemporary stage in the civilization development is characterized by the globalization of all the spheres and levels of human activities. In these conditions the world community does not have a greater problem both in its importance and in its scale than the problem of stable development of the planetary biosphere. The catastrophic signs of threat to human life are presently obvious. The problem of steady development of the planet was first set in the order-paper of the United Nations Conference on Environment and Development, which took place in 1992 in Rio de Janeiro (Brazil). At this conference the first integral program of actions was formulated — the joint all-planetary strategy. Its essence consists in the preservation of the biosphere — the ecological system of Earth, the stability and viability of which to a great extent depends on the richness and variety of the living species, that provides the stable development of our planet. A special place in the preservation of the biosphere belongs to the plants. They make the most essential autotrophic component of the biosphere — the unique original source of all its functional levels, and the existence of the human beings. It is the stability of the natural vegetable associations — phytocenoses — a surprising property of nature, which supports the stability of the biosphere on the whole and to a great extent compensates for even intensive harm done to the nature by the mankind. The preservation of the species variety is possible only on the basis of biological agriculture.

When the people primarily recognised their place in nature, this resulted in the forming of the behavioural paradigm of "determined biocentrism", based on the practically complete dependence of human beings on the ecological factors and natural resources. Later the philosophy of the humanity and the philosophy of nature were separated and developed independently of each other. As a result, anthropocentrism was the dominating philosophy of the human attitude toward nature for a long time. The main ethical principle in the transition from anthropocentrism to the "conscious biocentrism" is the respect for life on the whole as the basis of the biosphere existence. Therefore the survival of the humanity is possible only on the condition of its unity with all the "living matter", which requires the new attitude toward nature and the new style of thinking in the "human beings — nature" relations. The world outlook transformations concern, foremost,

the appearance of new ethical-ecological attitudes, which can be generalized in a few positions. It is necessary to recognise the limits of people's reconstructive activity in nature, that is, the impermissibility of destroying the biogenic constants of the biosphere. It is necessary to form a nature-integral behavioural dominant as an element of the ecological culture. Strict control of the society over the development and aims of using the abiogenic processes in the material production is also obligatory. The reason of this consists in the disparity between the power supply of abiogenic natural elements and processes, on one hand, and the biogenic potential of the biosphere, on the other. It is impermissible to change the composition and structure of the living matter of the biosphere by introducing artificially created abiogenic products and preparations to the biotic food chains.

We have grounds to say that the eco-ethics in the system of global bioethics is one of the most essential and at the same time one of the least developed aspects of philosophical awareness of the situation in which the mankind is. The update and modification of the ecological world outlook is the basis for uniting people into a planetary ecologic community with the purpose of overcoming the catastrophic consequences of the global ecological crisis.

An extremely important philosophical aspect of the problem consists in the discussion of a connection existing between the global ecological crisis and the noosphere formation. According to the conception of academician V. I. Vernadskiy the noosphere develops in the process of the biosphere transformation and its transition to a qualitatively new state. It was assumed that the human intellect as a powerful planetary geological force, is able to put in order the natural and social environment and result in the more refined forms of existence. In this context the forming of the noosphere appeared to be a systematic and conscious transformation of the biosphere with the purpose of solving the fundamental problems of the humanity in a new way, and was expected to bring undoubted benefit. The Russian theoretician of cosmic flights K. E. Tsiolkovskiy in his conception of cosmism considered the noosphere as a state of common wellbeing, harmony and victory over evil. In the understanding of academician V. I. Vernadskiy the noosphere is an incarnation of the moral intellect, which shows up in all forms of being: "Truth, beauty and good are united in the noosphere."

However, the real practice of noogenesis turned out to be not so good as it was expected. In the process of transforming the nature and the environment, the consequences of the people's intellectual and physical work have changed the conditions of the life on the planet and made the global ecological crisis a component part of the noosphere. People have created most complicated technical equipment, and developed new forms of psychological de-

pendence: computer, TV and internet addictions. Virtual reality was created, which can influence the human behaviour. Elements of artificial intelligence were developed and the prospects of further researches in this direction were defined. Computers now play not only an auxiliary role, they are becoming equal participants of the intellectual intercourse and in the prospect they will be able to make independent decisions. Living beings are transformed into virtual reality, the culture is replaced by a system of rationalistic constructions and is gradually reduced to science and techniques. Spirituality is reduced to reason, values are replaced by practical aims. The principles of benefit, liberalism and calculation prevail. There are tendencies to the humanity transition to the dead-lock ways of development, when the reproduction will be replaced by cloning, love — by the technique of sexual intercourse, the teaching — by training, and the labour — by automation.

Thus, the development of the noosphere as a change of the content of the planetary processes in the world enveloped by the people's intellectual activity, takes place parallel to the origin of a life threatening crisis. The destructive consequences of the noosphere crisis are enormous and its outcome is unforeseeable. The noosphere as a reality became an artificial environment, which constricts and narrows the natural habitat of the biological existence. The forming of such an artificial environment opened before the people unprecedented possibilities for increasing their financial well-being, comfort and safety, and raised their intellect to a new level of development. At the same time the processes of noogenesis resulted in the pollution of water and atmosphere, degradation of soil, environment, flora and fauna, i.e. to everything that made the object of the global ecological crisis. It turned out that unlike the biosphere, the noosphere does not have any protective or control mechanisms. The threat of the noosphere destruction and the role of the mankind with its imperfect political and social structures, economic technologies and psychological characteristics in this process became obvious. The human activities became instrumental in the completion of the cycle "birth — development — senescence — death" of the noosphere. From such world outlook positions the strengthening of spirituality and humanism becomes the major method of overcoming the noosphere crisis.

Unfortunately, in the new reality the former bioethical principles, methods and theories are not adequate enough. For the preservation of all the living creatures — people, flora, fauna, all the nature and the eco-system as a whole — new ethics is needed. It is appropriate to name this ethics *nooethics* and to understand it as the moral rules of conduct in the noosphere. The nooethics must become one of the new protective and control mechanisms of all the constituents of the noosphere — the planet Earth, humanity and the biosphere transformed by it. The global responsibility of the humanity

for the existence of life on Earth (in the noosphere after V. I Vernadskiy) presumably makes the deep destiny of the people and their life according to the moral principles of good, mercy, compassion and harmony with themselves and the world around them.

As the synonyms of the *noosphere* it is possible to use the concepts of *technosphere, ratiosphere, infosphere.* In any case, the essence of the conflict consists in the contradictions between the natural and artificial in the area of human beings dwelling, between the high intellect and unreasonable conduct of separate members of the society, which are ready to pay with their own life for the shallow, optional and doubtful comforts and pleasures of existence.

Section X
THE SOCIAL ETHICS OF MEDICINE

"To be happy with the happiness of others — this is the real happiness and the earthlyideal of life for everyone, who chooses the medical profession."

M. I. Pirogov

SOCIAL JUSTICE AND THE SOCIO-ETHICAL OBLIGATIONS

The conception of social morals is absent in the Hippocratic Oath. It focuses on providing a patient's wellbeing on the basis of ethically correct relations between a doctor and a patient. Ancient medicine was not oriented at achieving wellbeing and health of other persons or the society as a whole. The traditions of individualism to a great extent are preserved in the modern medical ethics and the medical workers' professional oaths. For example, the Declaration of Geneva contains a clause which actually confirms the exceptional position of an individual patient: "The health of my patient will be my first consideration".

The modern medical ethics since the second half of the XX-th century began its movement from the traditions of Hippocrates, based on the principles of beneficence and non-malfeasance, to the ethics of respect for personality with the balance of rights and duties and the observance of fundamental principles of autonomy, veracity, fidelity and prohibition of murder. The ideas of beneficence and non-malfeasance stopped to be the core of medical ethics, and during a certain period the ethics of respect for personality began to prevail. However, the new ethical conception still remained directed at the individual relations between a patient and a doctor — for instance, the issues of confidentiality, informed consent, and care of a dying patient. It would seem that in the whole world there is only one doctor and one patient. Ethical codes and guidelines for nurses and other medical professionals have also remained oriented at an individual patient.

The essence of the moral problem mainly consisted in determining how should a patient be treated. The discussions between the supporters of the Hippocratic ethics and the supporters of the ethics of respect for personality took place within the framework of the traditions of individualism. In fact, the discussions concerned the confronting of the principles, based on the estimation of the consequences (individual Hippocratic utility in the forms of beneficence and non-malfeasance) and the principles, based on duties (ethics of respect for personality).

The prevalence of the ethics of respect for personality with its principles of autonomy, veracity, fidelity and prohibition of murder turned out to be temporal, because a new tendency appeared in the medical ethics. The question concerns the movement of the ethical ideas from the individual to a more social model. People understood that the Hippocratic traditions and the ethics of respect for personality, in fact, ignore the duties in relation to a third party. It became obvious that the modern medicine must consider the necessity of distributing the limited resources of health services, establishing fair principles of access to the hi-tech methods of diagnostics and treatment, and also of carrying out clinical tests, the purpose of which consists not in achieving the wellbeing of an individual patient, but in receiving knowledge and experience in the interests of the society. As a result, along with the Hippocratic principle of *individual benefit*, the understanding of the ethical importance of the *social benefit* principle was formed. The social benefit is a principle based on the estimation of consequences and gives the total estimation of subjective and objective beneficence and non-malfeasance. The question concerns the consideration of all good and evil for all parts involved rather than just for an individual patient. The purpose consists in receiving the greatest aggregate of good. The social benefit principle became an object of analysis from the positions of "cost and gain" standard. In this analysis an attempt is made to define the potential gain and potential cost (economic, social, and medical) of the alternative use of resources. Then the results of analysis help to choose the alternative, in which the greatest benefit (gain) for a unit of cost is achieved.

The social benefit principle provides the social application of subjective and objective beneficence and non-malfeasance in relation to all potentially involved participants. The social utility reminds the principle of maximal increase of individual benefit after Hippocrates but differs in not being limited to an individual patient.

The critics of the social benefit principle appeal to the unsolved problems of the quantitative estimation of the degree of benefit. The quantitative estimation of the maximal benefit is extremely difficult because the concept of benefit unites most various subjective benefits, such as the removal of pain, increase of the social adjustment level, sustentation of a

hopeless patient's life till a certain event important for his/her family, or the removal of the psychological suffering. Nevertheless, the organizers of health care have developed and successfully approbated different scales, which quantitatively reflect the quality of life and the state of health in comparison to the scientifically estimated efficiency of medical technologies and their costs. As a result, there is a possibility to calculate the standard, which compares the benefit from the use of a certain medical technology with its negative influence on the quality of life ("*correlation of benefit and harm*"), and also the standard, which compares the benefit and cost of a specific medical interference ("*correlation of cost and benefit*").

The methodology of quantitative comparison of different medical technologies efficiency with scales and correlations, unfortunately, does not concern the problem of resources of the health services system. In accordance with the social benefit principle, the actions which provide a maximal general benefit to a unit of expended resources are morally correct. However, in the aspiration to increase the general social benefit the fact that the attained benefit is very unevenly distributed can escape notice. For example, the habitants of rural regions and small towns have a worse access to medical services than the habitants of large cities: the health care programs of the cities provide a higher level of social benefit to a unit of investments.

Naturally, there is a moral problem in relation to the ethics of such priorities. It can turn out that the most effective system of health protection is not the most fair and honest one. The moral disagreement with the distribution of the medical resources on the basis of attaining the maximal general benefit resulted in the formulation of the principle, which gives much attention to the distribution based on the *principle of social justice*. This principle is grounded on the estimation of duties and provides respect for the personality at the social level (Table 2). The principle of social justice means that people in identical situations must get identical benefits. In other words, people must have equal access to wellbeing. In the field of health protection this is usually interpreted as fair distribution of medical and social services for the provision of such medical necessities as prevention of death, treatment, delivery from suffering, provision of an acceptable quality of life, etc. The key position of the principle of social justice is the statement that the distribution of resources in accordance with the needs is an ethical duty, even if it is not accompanied with the maximal general social benefit. The practical realization of the principle of social justice is related to the identification of people who are in a greatest need for medical care presently or during all their life.

Certain types of medical services, such as removing sharp pain, therapy of acute curable diseases, granting the preventive technologies (such as immunization) can be justly distributed if they are rendered, foremost, to

the people, who have the greatest need in them at a concrete moment. Other medical services can be justly distributed, if they are provided to people who have a greatest need in them during all their lifetime.

The decision on the distribution of medical resources must be flexible and based on the balance with other ethical principles. The principle of mechanical equalising is unacceptable because it can bring all the patients in the category of extremely needing medical help. All the dead people are equal to each other, and a supporter of the equalising social justice must explain what other principles must be taken into account to avoid such an outcome. For example, there is a (debatable) point of view that if a person voluntarily chooses an unhealthy life style, he/she has less rights to receiving medical resources than the adherents of a healthy life style.

The distribution of the health protection resources is undoubtedly the most dramatic field in the medical ethics. The contradictions are intensified by the escalation of charges for health care, by the growth of costs of the medical technologies and management. People often fail to notice that constant reference to complex social indexes, such as the expected life-span or infantile death rates, results in an uneven grounding of the growth of the aggregate health of population as a leading, morally justified goal. No due attention is given to enormous distinctions in profits and education, and to the existence of racial and international distinctions.

The insufficiency of finances for medical help in all the countries in the world results in the necessity of rationing the medical interferences, which means shortening the expenditures for ineffective types of medical services and concentrating the efforts on granting equal access for the citizens to the most effective medical technologies. The situation implies that some inter-

Table 2. **Ethical Principles**

Principles	Based on the regard of consequences	Based on the regard of duties
Individual	Benefit after Hippocrates (subjective and objective): beneficence; non-malfeasance.	Ethics of respect for the personality: veracity; autonomy; fidelity; prohibition of murder
Social	Social benefit (subjective and objective)	Social justice

ferences are inaccessible for the patients because there is not enough means for them, so rationing is the only way to use the limited resources justly. The word *rationing* can be interpreted as economic, limited, thrifty use. Rationing implies not only abstaining from ineffective interferences but foremost — conscious, considered limitation in the access to useful treatment. In poor countries it concerns almost all the types of medical care, and in the rich countries it is usually limited by expensive types of help or medical services for separate groups of citizens. It is manifested in queues which take so much time that it is impossible to get treatment in reasonable terms; in bureaucratic obstacles which prevent people from obtaining certain types of treatment; in special forms of financing of some types of help, which are hard to receive; or in the exclusion of separate types of help (for example, prosthodontics) from the lists of free of charge services. The cost of providing everything desirable in the field of medicine to everyone who would like to get such help exceeds the volume of the national product even in the most economically developed countries. Besides, it is necessary to take into account the moral obligations before the developing countries. Rationing in the everyday practice includes many types of expensive interferences — such as dialysis, transplantation, or intensive therapy.

Specialists in intensive therapy are prepared better than other doctors to estimate the prospects of treatment and to decide what patients should be placed in the intensive therapy wards. When making such decisions, they take into account such factors as the quality of life from the patient's point of view, probability of survival, convertibility of the acute disorder, and the nature of the chronic disorder. Old age on itself, at least in the developed countries, is considered to be an impermissible reason for the limitation of treatment. At the same time, both in the USA and in other countries, the majority of people more frequently agree to the abstention from intensive therapy in seriously sick old people than in younger people.

In the rationing of the hi-tech (expensive) medical technologies the choice of the principles of limitations is the most painful problem. It is quite clear that the refusal to grant medical help to the patient on the grounds of his/her insolvency inevitably results in the origin of serious ethical problems. If we acknowledge the necessity and inevitability of medical rationing, it is necessary to consider among the criteria of its application such circumstances as the quality of a patient's life, the probability of his/her death in a short time, etc. In this case the society must clearly designate the volume of medical services which are granted to the citizens within the limits of accepted socio-ethical obligations. The recognition of the necessity and inevitability of rationing the medical services can be the only justification of its application. The non-providing of the medical services, which a patient wishes and which are really indicated to him, is the key sign of the rationing. We should

exclude from this definition those clinical situations in which a patient wishes to get certain types of medical care which in his/her case are inadvisable and ineffective. On the other hand, some of the specialists in bioethics support the point of view that it is possible and necessary to avoid rationing in medicine at the expense of some articles of budget and by reforming the system of health services.

The question, whether a clinical doctor should consider the purpose of resources economy while he is at a patient's sick-bed, is ethically difficult. Two answers are possible in principle, none of which can be considered as absolutely preferable from the ethical point of view. On one hand, the situation when a doctor possesses the rights of an agent who distributes medical resources has some positive sides. A clinician knows well those spheres in the health protection system, which receive surplus financing and can be painlessly shortened. The removing of bureaucrats from the sphere of decision-making is an advantage. Some doctors see serious advantages in going beyond the limits of traditional individual ethical principles and including social principles in the moral mandate of their professional responsibilities. However, there are some strong objections against this approach.

From the practical point of view, it is hard for a doctor to provide the process of the medical resources rationing. At a patient's sick-bed it would be not easy for a specialist, who had devoted his/her life to a certain sphere of clinical medicine, to compare the value of his own services with the value of other medical services. A surgeon will give preference to operative methods, a radiologist is aimed at radiotherapy, internists possess large experience of chemotherapy. None of them should have a right to decide when it is necessary to pass a patient's treatment to another specialist.

In the same way, it would be hard for a clinician to make a comparative estimation of medical problem solving and the possibilities of other, non-medical technologies. As the agents of social distribution of health protection resources, they would have to make optimal decisions whether it would be best to allot the means for the medical programs, or for the education, housing or foodstuffs provision.

Additional difficulties for a doctor as an agent of socially fair distribution of resources are connected with his traditional role of a patient's defender. Historically a doctor had followed the Hippocratic principles of beneficence and non-malfeasance, and his activities were in the field of individual usefulness and paternalism. A doctor's orientation at a patient remained, in spite of the tendencies to use the ethics of respect for personality, based on the assessment of duties. In the new situation a doctor's ethical duty consists not only in providing the maximal individual benefit but also in defend-

ing a patient's rights because a patient is still in the centre of a doctor's professional attention. Should a doctor undertake additional responsibility for the solving of social ethics problems, such as distribution of resources? Many people consider that a medical professional should not lose the role of a patient's defender.

An alternative consists in releasing a clinical doctor from participation in the solving of social ethics dilemmas, at least while treating the patients with typical diseases. At the same time in certain situations a doctor can not avoid the moral choice which includes socio-ethical principles, for example, when two or more patients require competitive clinical interference. The alternative releases a doctor from decision-making, which contradicts his role of a patient's defender. It enables the doctor to stay at the same moral height, as a barrister, which always remains on his/her client's side, even if there are grounds to think that the client is guilty. The society should decide more precisely who must be responsible for the socially fair distribution of resources, and what are the optimal mechanisms of decision-making, if a doctor will be excluded from solving this ethical problem.

Bioethics recognises the existence of socio-ethical obligations. The question is that the society is obliged to provide universal availability of a certain adequate level of medical services. If we agree with the moral obligation of granting at least a certain level of medical service, a question inevitably arises about the acceptable standard of this level. For example, must the society provide the availability of all the necessary services, or grant only the basic services? The answer depends on adhering to different conceptions of social justice, and also to other possible bases of socio-ethical obligations in the field of public health services. There are 3 main socio-political conceptions of justice, based on such moral values as freedom and equality. The criterion of benefit is also present in every conception because efficiency and practicality are important enough, but in none of the conceptions of social justice benefit as a moral value takes the dominant place.

1. The conception of justice founded on liberty values freedom as the greatest moral ideal. Every individual has moral rights to life, freedom and private property, which must be recognised and respected in every society. In accordance with this conception, the protection of the citizens' life, freedom and private property from violence and deception is the only function of the state. All the other spheres of social life are the object of individual responsibility and actions. The granting of any benefits to people who can not or do not want to get them on their own, according to this conception, is not a morally justified function of the state. Otherwise the state would have to take away certain benefits from some members of

society against their will and give them to others. This conception considers such actions as an unjustified limitation of the personal freedom. An individual owns his/her body and the results of his/her labour in the open economic market. Thus, nobody has a right to take away one's share of profits in order to render medical services or give other benefits to other people. In other words, this socio-political conception does not recognise an individual's moral right to receive health care or any socio-ethical obligations in this sphere.

2. The socialistic conception is a direct challenge to the conception founded on liberty. In spite of the variety of socialistic views, they are united by the recognition of social equality (the definition of which varies) as the greatest moral value, and the duty of a society and community, from the socialists' perspective, consists in providing this equality. From the positions of the socialistic conception, the special moral value of social equality justifies the possibility of limiting individual freedom for its achievement. Socialists criticize the conception of justice founded on liberty from the position of defending the ideals of social equality; they consider it impermissible to deny medical services, meals and other benefits to people, who are in a bad need of them. Socialists stress that the right to life and freedom is an empty declaration for those who have no means for food, habitation, or medical care; they argue against the freedom of the government to non-interference and insist on the existence of social obligations to support the wellbeing of the citizens of a country and provide them with the most essential necessities, including medical services.

3. The liberal conception of justice aims at connecting equality and freedom into one moral ideal. The fundamental moral principle of liberalism consists in the belief that those who have more than enough are obliged to help others who are in a sharp need of life essentials. In the economy the major value of liberalism is freedom and non-interference of the state in the economic processes. Liberals support the organizations which provide the basic necessities to the most needing members of society. The followers of liberalization are not against all the forms of social or economic inequality. They try to determine the morally acceptable limits of such inequality and its justification. For example, some liberals assert that inequality is justified in the limits which increase the general level of wellbeing in the society. Other liberals suppose that inequality in the distribution of the primary social benefits (profits, opportunities, medical services) has moral justification only in the limits, which are instrumental for the benefit of every member of society, especially the least well-to-do people.

Thus, not all the socio-political theories of justice recognise the existence of social obligations before the citizens. Moreover, some argu-

ments which support the necessity of socio-ethical obligations do not ground the position that the individuals have a right to health care. Reasons in the behalf of the existence of socio-ethical obligations to grant the citizens access to adequate health protection without a surplus financial burden are based: 1) on the special moral importance of health care; 2) on the fact, that many needs in medical services are insufficiently satisfied; 3) on the unrealistic nature of expectations that all citizens will be able to receive medical necessities at their personal expense because the costs of medical services are high and unforeseeable, and their distribution between different strata of population is unequal; 4) on the appeals to the moral values, according to which the modern society has no right to deny medical care to the citizens, if it has financial resources for this purpose.

The distribution of limited resources of health protection is carried out at the micro- and macro-levels. The decisions on the distribution at the micro-level are made by the hospital administrations, individual professionals or organisers of health protection and concern the granting of limited resources of health protection (for example, in the field of organs transplantation) to concrete patients. The decisions on the distribution at the macro-level is in the jurisdiction of the governments, bodies of legislative and executive power, bodies of health protection, insurance companies, funds and programs.

In the field of resources macro-distribution there are two fundamental questions. Foremost, it is necessary to define, what part of shareable economic resources of the state it is expedient to direct at the support of health protection and biomedical researches. The essence of this question consists in comparing the importance of medical services with other benefits. For example, modern medical technologies can save and prolong the life of many people who would be doomed to suffering and death not long ago. Should other social programs, for example, education, be shortened with the purpose of maximal prolongation of the human life? The other fundamental question in the distribution at the macro-level consists in defining how to divide the part of the national product, directed at the development of health protection and biomedical researches. What sum should be allotted to the needs of prophylactic medicine, what sums — to the treatment, to the development of new diagnostics and therapeutic equipment, and to the biomedical researches? Further it will be necessary to answer more private questions. For example, what stake will be allotted to the researches in the field of HIV/AIDS, oncology, cardiology, medical genetics, etc.? An important ethical problem is the determination of an optimal procedure of decision-making at the macro-level and the nature of moral values which should be considered.

THE MODELS OF HEALTH SERVICES AND THE PRACTICE OF BIOETHICS

Every system of health protection inevitably has to find answers to three primary questions:

1) What volume of means must the society allot to the health protection for the present and in the perspective?

2) How should these means be spent with maximal efficiency?

3) From what sources and how should these means be obtained?

The guaranteed volume of services directly depends on the level of expenses on health protection, which is fixed in the budget of a country as a certain share of the gross internal product. According to the data of the World Health Organization, 5% of the gross internal product is the possible minimum of expenses on the health protection. In the countries of Europe the share of health protection financing varies from 5.3% of the gross national product in Greece to 8% and more in Germany, France, Sweden and Netherlands.

The ratio of financial expenses in the system of health protection must be as follows: hospital help — 50%, outpatient-policlinic help — 40%, and the medical first-aid — 7–10%. In Ukraine, in spite of the yearly increase in the financing allotted to the health system development, its share in the volume of the gross internal product does not exceed 3.5%. Expensive treatment at the inpatient hospital departments and at the dispensaries remains the basic type of rendered medical services.

Financing at the expense of the society (budget, insurance funds, etc.) acts the dominant part in the organization of health protection in the developed and the majority of developing countries. The level of financing of health protection depends on the level of economic development of the country, and also on the method used for mobilizing resources for the needs of health protection: from general taxes, from the payments of economy subjects, or from the users' means. Proceeding from this, there are the following basic models of health protection financing:

1. *The state system*. It is financed (up to 90%) from the budgetary sources. The financing of medical services is planned within the general governmental charges. Great Britain is considered to be the standard of this model. The state system of medical services in this country was formed in the middle of the XX-th century and at once provided the citizens with an equal access to health services. It is important to mention that the private health protection and the insurance system were not abolished. The state system of health protection in Great Britain with its smaller expenses per capita than in the USA, Canada or Germany, was able to provide the outpa-

tient and inpatient help, maintenance of chronic patients, psychiatric help, oculist and dentist services, and the provision with medications. Considerable costs effectiveness was attained by the cutback of the administrative expenses. At the same time, the application of expensive technologies and equipment (for example, dialysis) is strictly controlled. There are some limitations in the choice of a family doctor, which refers a patient, if necessary, to the specialists for consulting.

The state model of health protection exists also in Greece, Portugal and preserves its dominant role in the states of the CIS.

2. *The budgetary-insurance system*. It is financed from the aimed payments of businessmen and working citizens (the Bismarck conception) and the state subsidies (the system of social insurance). Medical services are paid due to the deposits to the health protection funds. A payment made by an employer or a worker is the simplest type of deposit. Payments are based on solvency, and the access to the medical services depends on the need in them. A medical fund (or funds), as a rule, are independent of the state but operate within the framework of laws. The social insurance system grants a right to exactly stipulated types of services and establishes such shares of deposits and at such a level, which guaranty the use of this right. The financing from the off-budget funds of medical insurance prevails in Germany (78%), Italy (87%), France (71%), Sweden (91%), and Japan (73%). Governments carry out intent control over the system of health protection practically in all cases. The level of governmental control and regulation is aimed at providing the charges control (for example, by establishing a maximum level of insurance bonuses) with the purpose of providing justice and solidarity.

Germany is the standard of the budgetary-insurance system. Its unique experience is based on the creation of hospital funds, which include more than 100 of non-commercial and semiprivate organizations. The funds provide the choice of a doctor and the rendering of outpatient, inpatient, stomatological, psychiatric, and oculist help, provision with medications and payment of benefits in cash (for example, in connection with the birth of a child). The help to chronically ill old people and invalids is carried out with additional financing. On the whole, the charges on the health protection are lower than in America.

3. *The private enterprise system*. It is financed due to the provision of paid medical services and due to the means of medical insurance. The insured population pays a bonus to the insurer, and the sum of the bonus depends on the expected average cost of the medical services which they may need; subjects who are at a greater risk pay more. A patient's direct payment for services belongs neither to the insurance nor to mutual support. The patients pay for the services rendered to them in accordance with

the established tariffs. Such a system operates in the USA, Israel, South Korea, and Netherlands.

Presently Ukraine is in the process of reformation and perfection of the national health protection system. In the Soviet Union the provision of health care for the population was officially declared to be based on the principle of public funding, i.e. people were supposed to receive medical help regardless of their labour contribution, social origin, position in the society, nationality, place of habitation and other factors. This system had a purpose of providing social equality, oriented at the principle of the communist distribution "according to the needs". In spite of certain successes, the soviet system of health protection was far from the declared principle of social justice. The departmental medical institutions greatly differed from the district, city or rural hospitals. Among the elite departmental clinics there also was a hierarchy, built in accordance with the Communist party and state hierarchy of bureaucracy — the higher was a person's position in the hierarchy, the higher was the quality of medical service and the greater was the volume of rendered medical help. Naturally, the elite health protection by late 1980-s became one of the examples of the soviet state system injustice for the democratic forces.

A difficult situation has developed in Ukraine at the modern stage of the health system reformation. In accordance with the Constitution, the state has no right to abolish free medical services, all types of diagnostics, treatment and prophylaxis. Meantime, the state budget can not provide adequate financing of the required level of free medical care. In the situation when a medical institution is obliged to render all the volume of medical services free of charge, and the financing bodies are unable to recover its charges, the institution becomes insolvent. The state will be forced either to limit the volume of medical services rendered free of charge, or shorten the number of medical institutions. Voluntarily medical insurance and voluntarily donations also can not solve all the problems. Besides, presently in our country there are not so many people, who are able to pay for the diagnostics, treatment and other medical services. The considerable share of paid services in the health system actually brings the declared equal access to medical care to nought. In other words, Ukraine needs to work out the mechanisms of realizing the humane principles of equal access to medical services, which would be adequate to the conditions of the market economy. Besides the insurance medicine, one of the important directions in the reformation of the health system is the development and introduction of a national conception of primary medical-sanitary help (family medicine) and the introduction of the European principles of the higher education organization (the Bologna process). Creative analysis of the systems of health services in the economically developed countries, the experience of realis-

ing the social justice principle and the practice of fulfilling the socio-ethical commitments can promote the construction of a new model of health protection in Ukraine.

The Constitution of Ukraine, which guarantees the citizens' right to health protection and medical care, is the basis of the reformation (Supplement 18). "The Bases of Legislation of Ukraine on Health Protection" in accordance with article 4 recognise the health protection as a priority direction in the activity of the society and state, one of the main factors of survival and development of the Ukrainian people. The basic principles of the national model of health protection are:

— the observance of the human and citizens' rights and freedoms in the field of health protection and providing the state guarantees related to them;

— humanistic orientation, providing the priority of common to all mankind values over the class, national, group or individual interests, enhanced medical-social protection of the most vulnerable strata of the population;

— equality of the citizens' rights, democracy and general availability of the medical care and other services in the field of health protection;

— accordance to the tasks and level of the socio-economic and cultural development of the society, scientific grounding, material, technical and financial well-being;

— orientation at the modern standards of health and medical care, combination of national traditions and achievements with the world experience in the field of health protection;

— preventively-prophylactic nature, complex social, ecological and medical approach to the health protection;

— multiple economical bases of health protection and multi-channel nature of its financing, combination of state guarantees with de-monopolization and encouragement of enterprise and competition;

— decentralization of state administration, development of institutional self-government and the independence of health workers in the legal and contractual framework.

Regardless of the model of health protection, the practice of bioethics is characterized by the following general features:

1) the creation of committees on bioethics;

2) the organisation of bioethical consultations;

3) the development of the policy in bioethics and the publishing of appropriate guidelines and documents.

The committees on bioethics were created in early 1960-s in connection with the recognition of the ethical problem of selecting patients with chronic kidney insufficiency for the haemodialysis operation. Doctor B. Scribner was forced to initiate the collective determination of the criteria for selecting such patients the number of which considerably exceeded the number of expensive apparatuses.

In the 1970-s the functions of bioethical committees expanded in connection with the need of confirming the responsible diagnostic and prognostic conclusions of a doctor, which grounded the denial or stopping of the life-supporting treatment and a patient's right to death.

In the 1980-s the tasks of the bioethical committees were complemented by the discussion of various social and ethical problems in specific clinical cases. The development of the decision-making tactics in regard to incompetent patients can serve as an example. The methodology of identification, discussion and working out the bioethical problems was developed and perfected.

By the end of the XX-th — the beginning of the XXI-st centuries the strategy of bioethics development was finally formulated, fundamental documents and guidelines were prepared. In the wide understanding, bioethical committees were defined as a method of connection of the socio-ethical values with the medical practice. In the narrow understanding, bioethical committees serve as a method of protecting the patients' rights and wellbeing by collective decision-making in the field of medicine. The provisions of GSP, in which the bioethical committees were entrusted with the duty of providing the safety of all the participants of clinical research and the protection of the rights for all the society on the whole, were formulated in 1991. The control over the observation of ethical standards in the experiments involving animals can also be in the jurisdiction of the bioethical committees.

Bioethical committees function at different levels:

1. National committees on bioethics. In Ukraine at the national level the Committee on Bioethics at the Presidium of the National Academy of Science of Ukraine; the Committee on Bioethics at the Academy of Medical Science of Ukraine; and the Ethical Committee at the Ministry of Health of Ukraine were created.

2. Regional committees on bioethics spread their jurisdiction in a certain geographical territory.

3. Local committees on bioethics are created at the medical institutions, higher medical educational institutions, and research institutes.

The committees on bioethics must unite people which have an appropriate experience and qualification for the estimation of ethical problems in the field of biomedicine. Local committees on bioethics usually consist of 7 to 11 persons, among which there should be representatives of both genders, people of different age, professionals of different medical and non-medical disciplines, who know the international practice of human rights protection, public and religious figures who adhere to high principles and morals in their professional activity and life.

The members of the committees on bioethics must complete an initial training course and constantly promote their qualification in the field of

practical bioethics. Objective difficulties in the initial teaching and ongoing training are caused by significant distinctions in the base knowledge of the ethical problems and clinical medicine. The problems of discrepancy in the individual assessment of concrete cultural values by the members can arise. There are difficulties related to the voluntary nature of the membership in a committee, and with the necessity to create adequate training and methodological guidelines. In the process of training the members of a committee on bioethics must learn the bases of ethics and the technology of making ethical decisions. It is necessary to study the key principles of bioethics (such as beneficence, non-malfeasance, respect for autonomy and social justice), and also the basic ethical theories and the methods of bioethics. The members of a committee on bioethics should also master the method of system analysis of clinical cases.

After the completion of the training courses, the members of the committee on bioethics must provide the teaching of the specialists of the institution the bases of the discipline. The clinicians must be able to identify, understand and promote the working out of the practical ethical problems on the basis of sufficient professional, philosophical, social and legal knowledge and communication with their colleagues, patients and their relatives.

The teaching usually takes place on the basis of the clinical cases analysis, i.e. it is oriented at the patients. It includes seminars, lectures, discussions, and role modelling. It is appropriate to involve the patients and their family members in the process of teaching. The patients' rights and the principles of making medical decisions can be discussed.

The function of the committees on bioethics include the consulting of doctors at the institution, the patients and their family members. The practice of consulting raises an important question: are the committee recommendations obligatory or optional for execution, should they be registered in the written form as a medical document, or in any other way? The majority of bioethics suppose that the consulting conclusion has an optional nature, but it must be registered in a written form. For this reason the committees on bioethics are sometimes named consulting committees.

SUPPLEMENTS

Supplement 1

THE HIPPOCRATIC OATH *

I swear by Apollo Physician and Asclepius and Hygieia and Panaceia and all the gods and goddesses, making them my witnesses, that I will fulfill according to my ability and judgment this oath and this covenant: To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine; and to regard his offspring as equal to my brothers in male lineage and to teach them this art — if they desire to learn it — without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but no one else. I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice. I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect. Similarly I will not give to a woman an abortive remedy. In purity and holiness I will guard my life and my art. I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work. Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves.

What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must

* Translation from the Greek by Ludwig Edelstein. From The Hippocratic Oath: Text, Translation, and Interpretation, by Ludwig Edelstein. Baltimore: Johns Hopkins Press, 1943 *(note of the translator)*.

spread abroad, I will keep to myself, holding such things shameful to be spoken about. If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot.

Supplement 2

THE DECLARATION OF GENEVA
(The International Medical Oath)*

Adopted by the 2-nd General Assembly of the World Medical Association (Geneva, Switzerland) in September 1948 and amended by the 22nd World Medical Assembly (Sydney, Australia) in August 1968 and the 35th World Medical Assembly (Venice, Italy) in October 1983 [*and the 46th WMA General Assembly, Stockholm, Sweden, September 1994 and editorially revised at the 170th Council Session, Divonne-les-Bains, France, May 2005*]**.

At the time of being admitted as a member of the medical profession:

— I solemnly pledge to consecrate my life to the service of humanity.

— I will give to my teachers the respect and gratitude which is their due.

— I will practice my profession with conscience and dignity.

— The health of my patient will be my first consideration.

— I will respect the secrets which are confided in me, even after the patient has died.

— I will maintain by all the means in my power, the honour and the noble traditions of the medical profession.

— My colleagues will be my sisters and brothers.

— I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient.

— I will maintain the utmost respect for human life from its beginning even under threat, and I will not use my medical knowledge contrary to the laws of humanity.

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* From Wikipedia, the free encyclopaedia: http://en.wikipedia.org/wiki/Declaration_of_Geneva

** Note of the translator

[— I will maintain the utmost respect for human life;

— I will not use my medical knowledge contrary to the laws of humanity, even under threat] — 2005*;

I make these promises solemnly, freely and upon my honour.

Supplement 3

WORLD MEDICAL ASSOCIATION INTERNATIONAL CODE OF MEDICAL ETHICS**

Adopted by the 3rd General Assembly of the World Medical Association, London, England, October 1949 and amended by the 22nd World Medical Assembly (Sydney, Australia), August 1968 and the 35th World Medical Assembly (Venice, Italy), October 1983

DUTIES OF PHYSICIANS IN GENERAL

A physician shall always maintain the highest standards of professional conduct.

A physician shall not permit motives of profit to influence the free and independent exercise of professional judgment on behalf of patients.

A physician shall in all types of medical practice be dedicated to providing competent medical service in full technical and moral independence, with compassion and respect for human dignity.

A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.

The following practices are deemed to be unethical conduct:

a) Self advertising by physicians, unless permitted by the laws of the country and the Code of Ethics of the National Medical Association.

b) Paying or receiving any fee or any other consideration solely to procure the referral of a patient or for prescribing or referring a patient to any source.

A physician shall respect the rights of patients, of colleagues, and of other health professionals and shall safeguard patient confidences.

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* Note of the translator

** The World Medical Association, Policy, http://www.wma.net/e/policy/c8.htm

A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.

A physician shall use great caution in divulging discoveries or new techniques or treatment through non-professional channels.

A physician shall certify only that which he has personally verified.

DUTIES OF PHYSICIANS TO THE SICK

A physician shall always bear in mind the obligation of preserving human life.A physician shall owe his patients complete loyalty and all the resources of his science. Whenever an examination or treatment is beyond the physician's capacity he should summon another physician who has the necessary ability.

A physician shall preserve absolute confidentiality on all he knows about his patient even after the patient has died.

A physician shall give emergency care as a humanitarian duty unless he is assured that others are willing and able to give such care.

DUTIES OF PHYSICIANS TO EACH OTHER

A physician shall behave towards his colleagues as he would have them behave towards him.

A physician shall not entice patients from his colleagues.

A physician shall observe the principles of the "Declaration of Geneva" approved by the World Medical Association.

Supplement 4

THE MEDICAL OATH

At the time of being admitted as a member of the medical profession and having realised the importance of the duties entrusted to me, in the presence of my teachers and colleagues I solemnly pledge: to direct all my knowledge, power and skills to the cause of protecting and improving the people's health, treating and preventing diseases, to render medical help to everyone who needs it; to be invariably guided by the principles of general human morals in all my actions and thoughts, to be disinterested and considerate to the patients, to admit my errors, to continue the honourable traditions of the world medicine with dignity; to keep the medical secret, to abstain from using it to harm the people; to observe the rules of profession-

al ethics, not to conceal the truth if it will not harm the patient; to promote the upbringing of a physically and morally healthy generation with my own example, to consolidate the high ideals of mercy, love, goodwill and respect between people.

I pledge to carry the loyalty to this Oath through all my life.

Supplement 5

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*

The European Union, Oviedo, 04.IV.1997

CHAPTER I. THE GENERAL PROVISIONS

Article 1. Purpose and Object

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

Article 2. Primacy of the human being

The interests and welfare of the human being shall prevail over the sole interest of society or science.

Article 3. Equitable access to health care

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

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* http//conventions.coe.int/Treaty/EN/CadrelListeTraites.htm

Article 4. Professional standards

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

CHAPTER II. CONSENT

Article 5. General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

Article 6. Protection of persons not able to consent

1. Subject to Articles 17 and 20 of this Convention below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorisation procedure.

4. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 5.

5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

Article 7. Protection of persons who have mental disorder

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

Article 8. Emergency situation

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 9. Previously expressed wishes

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

CHAPTER III. PRIVATE LIFE AND RIGHT TO INFORMATION

Article 10. Private life and right to information

1. Everyone has the right to respect for private life in relation to information about his or her health.

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

CHAPTER IV. HUMAN GENOME

Article 11. Non-discrimination

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

Article 12. Predictive genetic tests

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

Article 13. Interventions on the human genome

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

Article 14. Non-selection of sex

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

CHAPTER V. SCIENTIFIC RESEARCH

Article 15. General rule

Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.

Article 16. The Protection of Persons Undergoing Research.

Research on a person may only be undertaken if all the following conditions are met:

1) there is no alternative of comparable effectiveness to research on humans;

2) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;

3) the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;

4) the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,

5) the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Article 17. Protection of persons not able to consent to research

1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:

1) the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled;

2) the results of the research have the potential to produce real and direct benefit to his or her health;

3) research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

4) the necessary authorisation provided for under Article 6 has been given specifically and in writing, and

5) the person concerned does not object.

2. Exceptionally and under the protective conditions prescribed by law,

where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs 1, 3, 4 and 5 above, and to the following additional conditions:

1) the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.

2) the research entails only minimal risk and minimal burden for the individual concerned.

Article 18. Research on embryos *in vitro*

1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

2. The creation of human embryos for research purposes is prohibited.

CHAPTER VI. ORGAN AND TISSUE REMOVAL FROM LIVING DONORS FOR TRANSPLANTATION PURPOSES

Article 19. General rule

1. Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

2. The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.

Article 20. Protection of persons not able to consent to organ removal

1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.

2. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:

1) there is no compatible donor available who has the capacity to consent,

2) the recipient is a brother or sister of the donor,

3) the donation must have the potential to be life-saving for the recipient,

4) the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the competent body,

5) the potential donor concerned does not object.

CHAPTER VII. PROHIBITION OF FINANCIAL GAIN AND DISPOSAL OF A PART OF THE HUMAN BODY

Article 21. Prohibition of financial gain

The human body and its parts shall not, as such, give rise to financial gain.

Article 22. Disposal of a removed part of the human body

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

CHAPTER VIII. INFRINGEMENTS OF THE PROVISIONS OF THE CONVENTION

Article 23. Infringement of the rights or principles

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Article 24. Compensation for undue damage

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 25. Sanctions

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

A DECLARATION ON THE PROMOTION OF PATIENTS' RIGHTS IN EUROPE*

Amsterdam, 1994

Section 1. Human Rights and Values in Health Care

1.1. Everyone has the right to respect of his or her person as a human being.

1.2. Everyone has the right to self-determination.

1.3. Everyone has the right to physical and mental integrity and to the security of his or her person.

1.4. Everyone has the right to respect for his or her privacy.

1.5. Everyone has the right to have his or her moral, cultural values, religious and philosophical convictions respected.

1.6. Everyone has the right to such protection of health as is afforded by appropriate measures for disease prevention and health care, and to the opportunity to pursue his or her own highest attainable level of health.

Section 2. Information

2.1. Information about health services and how best to use them is to be made available to the public in order to benefit all those concerned.

2.2. Patients have the right to be fully informed about their health status, including the medical facts about their condition; about the proposed medical procedures, together with the potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the effect of non-treatment; and about the diagnosis, prognosis and progress of treatment.

2.3. Information may only be withheld from patients exceptionally when there is good reason to believe that this information would, without any expectation of obvious positive effects, cause them serious harm.

2.4. Information must be communicated to the patient in a way appropriate to the latter's capacity for understanding, minimizing the use of unfamiliar technical terminology. If the patient does not speak the common language, some form of interpreting should be available.

2.5. Patients have the right not to be informed, at their explicit request.

2.6. Patients have the right to choose who, if any one, should be informed on their behalf.

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* The site of the World Health Organization www.who.int

2.7. Patients should have the possibility of obtaining a second opinion.

A "second opinion" is a concept which is widely spread in the modern medicine of the USA and Western Europe. The sources of the "second opinion" in diagnosing, making prognoses and choosing the optimal method of treatment are medical specialists, whom a patient consults independently from his/her treating doctor, if he/she is uncertain in the correctness of the diagnosis or treatment, or if the pending choice of the treatment tactics can have a very serious outcome (for example, a mutilating operation).

2.8. When admitted to a health care establishment, patients should be informed of the identity and professional status of the health care providers taking care of them and of any rules and routines which would bear on their stay and care.

2.9. Patients should be able to request and be given a written summary of their diagnosis, treatment and care on discharge from a health care establishment.

Section 3. Informed Consent

3.1. The informed consent of the patients is a prerequisite for any medical intervention.

3.2. A patient has the right to refuse or to halt a medical intervention. The implications of refusing or halting such an intervention must be carefully explained to the patient.

3.3. When a patient is unable to express his or her will and a medical intervention is urgently needed, the consent of the patient may be presumed, unless it is obvious from a previously declared expression of will that consent would be refused in the situation.

3.4. When the consent of a legal representative is required and the proposed intervention is urgently needed that intervention may be made if it is not possible to obtain, in time, the representative's consent.

3.5. When the consent of a legal representative is required, patients (whether minor or adult) must nevertheless be involved in the decision-making process to the fullest extent which their capacity allows.

3.6. If a legal representative refuses to give consent and the physician or other provider is of the opinion that the intervention is in the interest of the patient, then the decision must be referred to a court or some form if arbitration.

3.7. In all other situations where the patient is unable to give informed consent and where there is no legal representative or representative designated by the patient for this purpose, appropriate measures should be taken to provide for a substitute decision making process, taking into account what is known and, so far as possible, what may be presumed about the wishes of the patient.

3.8. The consent of the patient is required for the preservation and use of all substances of the human body. Consent may be presumed when the substances are to be used in the current course of diagnosis, treatment and care of that patient.

3.9. The informed consent of the patient is needed for participation in clinical teaching.

Section 4. Confidentiality and Privacy

4.1. All information about a patient's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind must be kept confidential, even after death.

4.2. Confidential information can only be disclosed if the patient gives explicit consent or if the law expressly provides for this. Consent may be presumed where disclosure is to other health care providers involved in that patient's treatment.

4.3. All identifiable patient data must be protected. The protection of the data must be appropriate to the manner of their storage. Human substances from which identifiable data can be derived must be likewise protected.

4.4. Patients have the right of access to their medical files and technical records and to any other files and records pertaining to their diagnosis, treatment and care and to receive a copy of their own files and records or parts thereof. Such access excludes data concerning third parties.

4.5. Patients have the right to require the correction, completion, deletion, clarification and/or updating of personal and medical data concerning them which are inaccurate, incomplete, ambiguous or outdated, or which are not relevant to the purposes of diagnosis, treatment and care.

4.6. There can be no intrusion into a patient's private and family life unless and only if, in addition to patient consenting to it, it can be justified as necessary to the patient's diagnosis, treatment and care.

4.7. Medical interventions may only be carried out when there is proper respect shown for the privacy of the individual. This means that a given intervention may be carried out only in the presence of those persons who are necessary for the intervention unless the patient consents or requests otherwise.

4.8. Patients admitted to health care establishments have to right to expect physical facilities which ensure privacy, particularly when health care providers are offering them personal care or carrying out examinations and treatment.

Section 5. Care and Treatment

5.1. Everyone has the right to receive such health care as is appropriate to his or her health needs, including preventive care and activities aimed at

health promotion. Services should be continuously available and accessible to all equitably, without discrimination and according to the financial, human and material resources which can be made available in a given society.

5.2. Patients have a collective right to some form of representation at each level of the health care system in matters pertaining to the planning and evaluation of services, including the range, quality and functioning of the care provided.

5.3. Patients have the right to a quality of care which is marked both by high technical standards and by a humane relationship between the patient and health care providers.

5.4. Patients have the right to continuity of care, including cooperation between all health care providers and/or establishments which may be involved in their diagnosis, treatment and care.

5.5. In circumstances where a choice must be made by providers between potential patients for a particular treatment which is in limited supply, all such patients are entitled to a fair selection procedure for that treatment. That choice must be based on medical criteria and made without dscrimination.

5.6. Patients have the right to choose and change their own physician or other health care provider and health care establishment, provided that it is compatible with the functioning of the health care system.

5.7. Patients for whom there are no longer medical grounds for continued stay in a health care establishment are entitled to a full explanation before they can be transferred to another establishment or sent home. Transfer can only take place after another health care establishment has agreed to accept the patient. Where the patient is discharged to home and when his or her condition so requires, community and domiciliary services should be available.

5.8. Patients have the right to be treated with dignity in relation to their diagnosis, treatment and care, which should be rendered with respect for their culture and values.

5.9. Patients have the right to enjoy support from family, relatives and friends during the course of care and treatment and to receive spiritual support and guidance at all times.

5.10. Patients have the right to relief of their suffering according to the current state of knowledge.

5.11. Patients have the right to humane terminal care and to die in dignity.

Section 6. The Patients' Rights

6.1. The exercise of the rights set forth in this document implies that appropriate means are established for this purpose.

6.2. The enjoyment of these rights shall be secured without discrimination.

6.3. In the exercise of these rights, patients shall be subjected only to such limitations as are compatible with human rights instruments and in accordance with a procedure prescribed by law.

6.4. If patients cannot avail themselves of the rights set forth in this document, these rights should be exercised by their legal representative or by a person designated by the patient for that purpose; where neither a legal representative nor a personal surrogate has been appointed, other measures for representation of those patients should be taken.

6.5. Patients must have access to such information and advice which will enable them to exercise the rights set forth in this document. Where patients feel that their rights have not been respected they should be able to lodge a complaint. In addition to recourse to the courts, there should be independent mechanisms at institutional and other levels to facilitate the processes of lodging, mediating and adjudicating complaints. These mechanisms would, *inter alia*, ensure that information relating to complaints procedures was available to patients and that an independent person was available and accessible to them for consultation regarding the most appropriate course of action to take. These mechanisms should further ensure that, where necessary, assistance and advocacy on behalf of the patient would be made available. Patients have the right to have their complaints examined and dealt with in a thorough, just, effective and prompt way and to be informed about their outcome.

Supplement 7

BASES OF THE LAW OF UKRAINE ON HEALTH CARE

Article 42. General conditions of medical interference

Medical interference (application of methods of diagnostics, prophylaxis or treatment, related to the influence on the human organism) is allowed only if it can not inflict harm to the patient's health.

Article 43. Consent to medical interference

In urgent situations, if there is a real threat to a patient's life, the consent of the patient or his/her legal representatives for the medical interference is not required.

***Article 45*. Medical-biological experiments on people**

The execution of medical-biological experiments on people is allowed with a publicly useful purpose on the conditions of their scientific validity, predominance of the possible success over the risk of causing negative consequences for the health or life, publicity of the experiment, completely informed (on the requirements of its execution) and voluntarily consent of the person subject to the experiment, and on the condition of keeping (if necessary) the medical secret. The execution of research experiments is forbidden on patients, prisoners or prisoners of war, as well as therapeutic experiments on people whose disease is not directly connected with the purpose of experiment.

Supplement 8

DECLARATION ON EUTHANASIA

(adopted by the 39th World Medical Assembly, Madrid, Spain, October 1987 and reaffirmed at the 170th Council Session, Divonne-les-Bains, France, May 2005) *

Euthanasia, that is the act of deliberately ending the life of a patient, even at the patient's own request or at the request of close relatives, is unethical. This does not prevent the physician from respecting the desire of a patient to allow the natural process of death to follow its course in the terminal phase of sickness.

* The World Medical Association, Policy. http://www.wma.net/e/policy/e13.htm

THE DECLARATION ON TERMINAL ILLNESS OF VENICE

*Adopted by the 35th World Medical Assembly Venice, Italy, October 1983**

1. The duty of the physician is to heal and, where possible, relieve suffering and act to protect the best interests of his patients.

2. There shall be no exception to this principle (c.1) even in the case of incurable disease or malformation.

3. This principle does not preclude application of the following rules:

3.1. The physician may relieve suffering of a terminally ill patient by withholding treatment with the consent of the patient or his immediate family if unable to express his will.

Withholding of treatment does not free the physician from his obligation to assist the dying person and give him the necessary medicaments to mitigate the terminal phase of his illness.

3.2. The physician shall refrain from employing any extraordinary means which would prove of no benefit for the patient.

3.3. The physician may, when the patient cannot reverse the final process of cessation of vital functions, apply such artificial means as are necessary to keep organs active for transplantation provided he acts in accordance with the laws of the country or by virtue of a formal consent given by the responsible person and provided the certification of death or the irreversibility of vital activity had been made by physicians unconnected with the transplantation and the patient receiving treatment. These artificial means shall not be paid for by the donor or his relatives. Physicians treating the donor shall be totally independent of those treating the recipient and of the recipient himself.

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* The World Medical Association http://www.wma.net/e/policy/handbook.htm

STATEMENT ON PERSISTENT VEGETATIVE STATE

*Adopted by the 41st World Medical Assembly Hong Kong, September 1989 and rescinded at the WMA General Assembly, Santiago 2005**

Preamble

Present requirements of health reporting fails to provide an accurate estimate of the incidence and prevalence of worldwide individuals in a persistent vegetative state (PVS). Ten years ago, a prevalence of 2 to 3 per 100,000 was estimated for Japan. It seems likely that the absolute number of such cases has risen appreciably as a consequence of current practices in critical medicine, cardio-respiratory support, parenteral feeding, and control of infections in severely brain damaged patients. How to deal with this emotionally painful, financially costly, and generally unwanted outcome of modern medical treatment is an increasing problem.

Persistent Vegetative State

Pathologic loss of consciousness may follow a variety of insults to the brain including, among others, nutritional insufficiency, poisoning, stroke, infections, direct physical injury, or degenerative disease. Abrupt loss of consciousness usually consists of an acute sleep-like state of unarousability called coma that may be followed either by varying degrees of recovery or severe, chronic neurological impairment. Persons with overwhelming damage to the cerebral hemispheres commonly pass into a chronic state of unconsciousness called the vegetative state in which the body cyclically awakens and sleeps but expresses no behavioural or cerebral metabolic evidence of possessing cognitive function or of being able to respond in a learned manner to external events or stimuli. This condition of total cognitive loss can follow acute injuries causing coma or can develop more slowly as an end result of progressive structural disorders, such as Alzheimer's disease, that in their end stages also can destroy the psychological function of the cerebrum. When such cognitive loss lasts for more than a few weeks, the condition has been termed a persistent vegetative state (PVS) because the body retains the functions necessary to sustain vegetative survival. Recovery from the vegetative state is possible, especially during the first few days or weeks after onset, but the tragedy is that many persons in PVS live for many months or years if provided with nutritional and other supportive measures.

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* http://www.wma.net/e/policy/p11.htm

Recovery

Once qualified clinicians have determined that a person is awake but unaware, the permanence of the vegetative state depends on the nature of the brain injury, the duration of the period of unawareness, and the estimated prognosis. Some persons less than 35 years old with coma after head trauma, as well as an occasional patient with coma after intracranial haemorrhage, may recover very slowly; thus, what appears to be a PVS at one to three months after an event causing coma may in rare cases evolve into a lesser degree of impairment by six months. On the other hand, the chances of regaining independence after being vegetative for three months are vanishingly small. Rare exceptions are claimed, but some of these may have represented patients who entered an unrecognized locked-in state shortly after reawakening from a coma-causing injury. Ultimately, all have been severely disabled.

Guidelines

These rare examples notwithstanding, the data indicate that unawareness for six months predicts non-recovery or overwhelming disability with a high degree of certainty regardless of the nature of the insult to the brain. Therefore, a conservative criterion for the diagnosis of PVS would be observed unawareness for at least 12 months although cognitive recovery after six months is exceedingly rare in patients over 50.

The risk of prognostic error from widespread use of the above criterion is so small that a decision that incorporates it as a prognostic conclusion seems fully justifiable. A physician's determination that a person is unlikely to regain consciousness is the usual prelude to deliberations about withdrawing or withholding life support. Although the family may be the first to raise the issue, until a physician has ventured an opinion about prognosis, the matter of withholding treatment is not generally considered. Once the question of withholding or withdrawing life support has been raised, its legal and ethical dimensions must be considered.

THE STATEMENT ON THE RIGHT OF A WOMAN TO CONTRACEPTION*

Adopted by the 46th World Medical Assembly, Stockholm, Sweden, September, 1994

The World Medical Association recognises that unwanted pregnancies may have a significant and ongoing effect on women's health and on the health of their children. Thus, the ability to regulate and control fertility should be regarded as a principal component of the women's physical and mental health and social wellbeing.

A strong but largely unmet demand for fertility control exists in many developing countries. In these countries, many women who are not currently using contraception wish to avoid pregnancy.

Contraception can prevent premature deaths of women from the consequences of unwanted pregnancies. Optimal planning of childbearing also will contribute to infant and child survival.

Even in the cases when political, religious and other groups in a country are against using contraception, separate women who live in these countries must have a right of choice in using contraception.

The World Medical Association asserts that all women should be permitted to opt for fertility control by choice rather than by chance. The WMA asserts that it is a woman's right, regardless of nationality, social rank or creed to exercise individual choice in regard to contraception. The women should have access to all the medical and social counselling necessary to get maximum benefit from family planning.

THE DECLARATION "ON FAMILY PLANNING"

Adopted in 1967 by the World Medical Assembly in Madrid, confirmed in 1969 and supplemented in 1983.

1. The World Medical Association (WMA) approves of the family plan-

* The text of the WMA statements presented in Supplements 11 and 12, namely those on "The Right of a Woman to Contraception" and on "Family Planning" were amalgamated in the World Medical Association Statement on Family Planning and the Right of a Woman to Contraception adopted by the 48th General Assembly Somerset West, Republic of South Africa, October 1996. http://www.wma.net/e/policy/handbook.htm

ning conception and recommends that each national medical association actively promote family planning and to ensure high standards of delivery of materials and information on the appropriate methods.

2. The objective of family planning is the improvement and enrichment of human life, and not the imposing of any restrictions. Family planning can help to assure greater opportunity for individuals to reach their full potential. To enjoy one of the main human rights in the full measure, parents should have the knowledge and master the methods of family planning, make the decisions concerning the number of children and the time intervals between their birth consciously and independently.

3. The WMA offers all the interested organisations collaboration in the field of medical and hygienic aspects of family planning, its help in the selection of experts in family planning, and in the organisation of training, necessary experimenting and research in this field.

4. The WMA affirms its desire to encourage any organizations to conduct conferences, symposia, or studies on relevant aspects of family planning.

5. The WMA recommends to include family planning issues in the programs of higher medical education as a part of courses concerning the mother and child health care.

Supplement 13

STATEMENT ON GENETIC COUNSELING AND GENETIC ENGINEERING*

Adopted by the 39th World Medical Assembly (Madrid, Spain,1987) and rescinded at the WMA General Assembly, Santiago 2005

Genetic Counseling. There are two primary areas of genetic diagnosis:

1) screening or evaluating prospective parents before conception for genetic disease to predict the likelihood of conceiving an affected child; and

2) in utero testing after conception, such as ultrasonography, amniocentesis, and fetoscopy, to determine the condition of the fetus.

Physicians engaged in genetic counseling are ethically obligated to provide prospective parents with the basis for an informed decision for childbearing. In providing information to couples who choose to reproduce,

* http://www.wma.net/e/policy/handbook.htm

physicians should adhere to the ethical requirements and the professional standards for medical practice in the community, as established by WMA National Medical Association and other appropriate medical organizations.

Technological developments have improved the accuracy of predicting and detecting genetic disorders. Where a genetic defect is found in the fetus, the prospective parents may, or may not, request an abortion. Physicians, for personal moral reasons may, or may not, oppose the provision of contraception, sterilization or abortion as part of the genetic counseling services. Whether they advocate or oppose providing such services, physicians should avoid the imposition of their personal moral values and the substitution of their own moral judgment for that of the prospective parents.

Physicians who consider contraception, sterilization and abortion to be in conflict with their moral values and conscience may choose not to provide genetic services. However, in appropriate circumstances, the physician is nevertheless obligated to alert prospective parents that a potential genetic problem does exist, and that the patient should seek medical genetic counseling from a qualified specialist.

Genetic Engineering. As genetic engineering research develops, appropriate guidance must be provided by the scientific community, medicine, industry, government and the public to regulate such research.

If and when gene replacement with Normal DNA becomes a practical reality for the treatment of human disorders, the World Medical Association urges that the following factors be considered:

1. If procedures are performed in research setting, reference should be made to the World Medical Association Declaration of Helsinki on biomedical research involving human subjects.

2. If procedures are performed in research setting, reference should be made to the World Medical Association Declaration of Helsinki on biomedical research involving human subjects.

3. Full discussion of the proposed procedure with the patient must be required. The consent of the patient or his legal representative must be informed, voluntary, and written.

4. There must be no hazardous or other unwanted virus on the viral DNA containing the replacement or corrective gene.

5. The inserted DNA must function under normal control within the recipient cell to prevent metabolic damage that could damage healthy tissue and the patient.

6. The effectiveness of the gene therapy should be evaluated as best as possible. This will include determination of the natural history of the disease and follow-up examination of subsequent generations.

7. Such procedures should be undertaken in the future only after careful evaluation of the availability and effectiveness of other possible therapy. If simpler and safer treatment is available, it should be pursued.

8. These considerations should be reviewed, as appropriate, as procedures and scientific information are developed in the future.

Supplement 14

UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

PREAMBLE

The Universal Declaration on the Human Genome and Human Rights was unanimously and by acclamation accepted by the General Conference of UNESCO at its 29th session of November 11, 1997. It became the first universal legal act in the field of biology. The balance attained in it between the guaranty of rights and basic freedoms observance and the necessity of providing the freedom of research is an indisputable merit of this document.

The general conference of UNESCO supplemented this Declaration with the resolution on its realization, in which the states-members are obligated to take proper measures in order to ratify the assistance in the realization of the principles proclaimed in it.

The moral obligation which the states undertook by approving The Universal Declaration on the Human Genome and Human Rights is a starting point: it has begun the process of becoming aware of the necessity to reflect on the ethics of science and technology in the world public. Now it is up to the states to provide the realization of this Declaration by the measures which they will decide to undertake, and by doing this to provide its intransient value.

UNESCO Director-General Federico Mayor

UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS*

The General Conference,

Recalling that the Preamble of UNESCO's Constitution refers to 'the democratic principles of the dignity, equality and mutual respect of men',

* http://portal.unesco.org

rejects any 'doctrine of the inequality of men and races', stipulates 'that the wide diffusion of culture, and the education of humanity for justice and liberty and peace are indispensable to the dignity of men and constitute a sacred duty which all the nations must fulfil in a spirit of mutual assistance and concern', proclaims that 'peace must be founded upon the intellectual and moral solidarity of mankind', and states that the Organization seeks to advance, 'through the educational and scientific and cultural relations of the peoples of the world, the objectives of international peace and of the common welfare of mankind for which the United Nations Organization was established and which its Charter proclaims,

Solemnly recalling its attachment to the universal principles of human rights, affirmed in particular in the Universal Declaration of Human Rights of 10 December 1948 and in the two International United Nations Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, in the United Nations Convention on the Prevention and Punishment of the Crime of Genocide of 9 December 1948, the International United Nations Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Declaration on the Rights of Mentally Retarded Persons of 20 December 1971, the United Nations Declaration on the Rights of Disabled Persons of 9 December 1975, the United Nations Convention on the Elimination of All Forms of Discrimination Against Women of 18 December 1979, the United Nations Declaration of Basic Principles of Justice for Victims of Crime and Abuse of Power of 29 November 1985, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Standard Rules on the Equalization of Opportunities for Persons with Disabilities of 20 December 1993, the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction of 16 December 1971, the UNESCO Convention against Discrimination in Education of 14 December 1960, the UNESCO Declaration of the Principles of International Cultural Co-operation of 4 November 1966, the UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the ILO Convention (No. 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958 and the ILO Convention (No. 169) concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989,

Bearing in mind, and without prejudice to, the international instruments which could have a bearing on the applications of genetics in the field of intellectual property, inter alia the Berne Convention for the Protection of Literary and Artistic Works of 9 September 1886 and the UNESCO Universal Copyright Convention of 6 September 1952, as last revised at Paris

on 24 July 1971, the Paris Convention for the Protection of Industrial Property of 20 March 1883, as last revised at Stockholm on 14 July 1967, the Budapest Treaty of the WIPO on International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures of 28 April 1977, and the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995,

Bearing in mind also the United Nations Convention on Biological Diversity of 5 June 1992 and emphasizing in that connection that the recognition of the genetic diversity of humanity must not give rise to any interpretation of a social or political nature which could call into question 'the inherent dignity and (...) the equal and inalienable rights of all members of the human family', in accordance with the Preamble to the Universal Declaration of Human Rights,

Recalling 22 C/Resolution 13.1, 23 C/Resolution 13.1, 24 C/Resolution 13.1, 25 C/Resolutions 5.2 and 7.3, 27 C/Resolution 5.15 and 28 C/Resolutions 0.12, 2.1 and 2.2, urging UNESCO to promote and develop ethical studies, and the actions arising out of them, on the consequences of scientific and technological progress in the fields of biology and genetics, within the framework of respect for human rights and fundamental freedoms,

Recognizing that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but emphasizing that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics,

Proclaims the principles that follow and adopts the present Declaration.

A. HUMAN DIGNITY AND THE HUMAN GENOME

Article 1

The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Article 2

(a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.

(b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

Article 3

The human genome, which by its nature evolves, is subject to mutations. It contains potentialities that are expressed differently according to each individual's natural and social environment, including the individual's state of health, living conditions, nutrition and education.

Article 4

The human genome in its natural state shall not give rise to financial gains.

B. RIGHTS OF THE PERSONS CONCERNED

Article 5

(a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.

(b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest.

(c) The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.

(d) In the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines.

(e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.

Article 6

No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.

Article 7

Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law.

Article 8

Every individual shall have the right, according to international and national law, to just reparation for any damage sustained as a direct and determining result of an intervention affecting his or her genome.

Article 9

In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights.

C. RESEARCH ON THE HUMAN GENOME

Article 10

No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.

Article 11

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.

Article 12

(a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.

(b) Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.

D. CONDITIONS FOR THE EXERCISE OF SCIENTIFIC ACTIVITY

Article 13

The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome because of its ethical and social implications. Public and private science policy-makers also have particular responsibilities in this respect.

Article 14

States should take appropriate measures to foster the intellectual and material conditions favourable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research, on the basis of the principles set out in this Declaration.

Article 15

States should take appropriate steps to provide the framework for the free exercise of Research on the human genome with due regard for the principles set out in this Declaration, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health. They should seek to ensure that research results are not used for non-peaceful purposes.

Article 16

States should recognize the value of promoting, at various levels, as appropriate, the establishment of independent, multidisciplinary and plural-

ist ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its applications.

E. SOLIDARITY AND INTERNATIONAL CO-OPERATION

Article 17

States should respect and promote the practice of solidarity towards individuals, families and population groups who are particularly vulnerable to or affected by disease or disability of a genetic character. They should foster, inter alia, research on the identification, prevention and treatment of genetically based and genetically influenced diseases, in particular rare as well as endemic diseases which affect large numbers of the world's population.

Article 18

States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

Article 19

(a) In the framework of international co-operation with developing countries, states should seek to encourage measures enabling:

(i) assessment of the risks and benefits pertaining to research on the human genome to be carried out and abuse to be prevented;

(ii) the capacity of developing countries to carry out research on human biology and genetics, taking into consideration their specific problems, to be developed and strengthened;

(iii) developing countries to benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all;

(iv) the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted.

(b) Relevant international organizations should support and promote the initiatives taken by states for the above-mentioned purposes.

F. PROMOTION OF THE PRINCIPLES SET OUT IN THE DECLARATION

Article 20

States should take appropriate measures to promote the principles set out in the Declaration, through education and relevant means, inter alia through the conduct of research and training in interdisciplinary fields and through the promotion of education in bioethics, at all levels, in particular for those responsible for science policies.

Article 21

States should take appropriate measures to encourage other forms of research, training and information dissemination conducive to raising the awareness of society and all of its members of their responsibilities regarding the fundamental issues relating to the defence of human dignity which may be raised by research in biology, in genetics and in medicine, and its applications. They should also undertake to facilitate on this subject an open international discussion, ensuring the free expression of various socio-cultural, religious and philosophical opinions.

G. IMPLEMENTATION OF THE DECLARATION

Article 22

States should make every effort to promote the principles set out in this Declaration and should, by means of all appropriate measures, promote their implementation.

Article 23

States should take appropriate measures to promote, through education, training and information dissemination, respect for the above-mentioned principles and to foster their recognition and effective application. States should also encourage exchanges and networks among independent ethics committees, as they are established, to foster full collaboration.

Article 24

The International Bioethics Committee of UNESCO 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. It should organize appropriate consul-

tations with parties concerned, such as vulnerable groups. It should make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration, in particular regarding the identification of practices that could be contrary to human dignity, such as germ-line interventions.

Article 25

Nothing in this Declaration may be interpreted as implying for any state, group or person any claim to engage in any activity or to perform any act contrary to human rights and fundamental freedoms, including the principles set out in this Declaration.

IMPLEMENTATION OF THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

The General Conference,

Considering the Universal Declaration on the Human Genome and Human Rights, which was adopted on this eleventh day of November 1997,

Noting that the considerations formulated by the Member States at the moment of the adoption of the Universal Declaration are relevant for the follow-up of the Declaration,

1. *Urges* Member States:

(a) in the light of the provisions of the Universal Declaration on the Human Genome and Human Rights, to take appropriate steps, including the introduction of legislation or regulations, to promote the principles set forth in the Declaration, and to promote their implementation;

(b) to keep the Director-General regularly informed of all measures they have taken for the implementation of the principles set forth in the Declaration;

2. *Invites* the Director-General:

(a) to convene as soon as possible after the twenty-ninth session of the General Conference an *ad hoc* working group with balanced geographical representation, comprised of representatives of Member States, with a view to advising him on the constitution and the tasks of the International Bioethics Committee with respect to the Universal Declaration and on the conditions, including the breadth of consultations, under which it will ensure the follow-up to the said Declaration, and to report on this to the Executive Board at its 154th session;

(b) to take the necessary steps to enable the International Bioethics Committee to ensure dissemination of and follow-up to the Declaration, and promotion of the principles set forth therein;

(c) to prepare for the General Conference a global report on the situation world-wide in the fields relevant to the Declaration, on the basis of information supplied by the Member States and other demonstrably trustworthy information gathered by whatever methods he may deem appropriate;

(d) to take due account, in the preparation of his global report, of the work of the organizations and agencies of the United Nations system, of other international organizations, and of the competent international non-governmental organizations;

(e) to submit his global report to the General Conference, along with whatever general observations and recommendations may be deemed necessary in order to promote the implementation of the Declaration.

Supplement 15

DECLARATION OF TOKYO*

Adopted by the 29th World Medical Assembly,
Tokyo, Japan, October 1975

Guidelines for Medical Doctors concerning Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment in relation to Detention and Imprisonment

Preamble

It is the privilege of the medical doctor to practice medicine in the service of humanity, to preserve and restore bodily and mental health without distinction as to persons, to comfort and to ease the suffering of his or her patients. The utmost respect for human life is to be maintained even under threat, and no use made of any medical knowledge contrary to the laws of humanity.

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* http://www.cirp.org/library/ethics/tokyo/ , www.wma.net/e/policy/b3.htm

For the purpose of this Declaration, torture is defined as the deliberate, systematic or wanton infliction of physical or mental suffering by one or more persons acting alone or on the orders of any authority, to force another person to yield information, to make a confession, or for any other reason.

Declaration

1. The doctor shall not countenance, condone or participate in the practice of torture or other forms of cruel, inhuman or degrading procedures, whatever the offence of which the victim of such procedure is suspected, accused or guilty, and whatever the victim's belief or motives, and in all situations, including armed conflict and civil strife.

2. The doctor shall not provide any premises, instruments, substances or knowledge to facilitate the practice of torture or other forms of cruel, inhuman or degrading treatment or to diminish the ability of the victim to resist such treatment.

3. The doctor shall not be present during any procedure during which torture or other forms of cruel, inhuman or degrading treatment are used or threatened.

4. A doctor must have complete clinical independence in deciding upon the care of a person for whom he or she is medically responsible. The doctor's fundamental role is to alleviate the distress of his or her fellow men, and no motive whether personal, collective or political shall prevail against this higher purpose.

5. Where a prisoner refuses nourishment and is considered by the doctor as capable of forming an unimpaired and rational judgement concerning the consequences of such voluntary refusal of nourishment, he or she shall not be fed artificially. The decision as to the capacity of the prisoner to form such a judgement should be confirmed by at least one other independent doctor. The consequences of the refusal of nourishment shall be explained by the doctor to the prisoner.

6. The World Medical Association will support, and should encourage the international community, the national medical associations and fellow doctors to support the doctor and his or her family in the face of threats or reprisals resulting from a refusal to condone the use of torture or other forms of cruel, inhuman or degrading treatment.

THE DECLARATION OF HELSINKI*

Adopted by the 18th WMA General Assembly (Helsinki, Finland, 1964)
Amended by the 29th WMA General Assembly (Tokyo, Japan, 1975),
35th WMA General Assembly (Venice, Italy, 1983),
41st WMA General Assembly (Hong Kong, 1989),
[48th WMA General Assembly (Somerset West, Republic of South Africa, 1996)
and the 52nd WMA General Assembly (Edinburgh, Scotland,2000).]

Guidelines to Physicians Who Carry Out Medical-Biological Research Involving Human Subjects

Introduction

It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.

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* http://www.wma.net/e/policy/b3.htm

In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.

Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

Basic Principles For All Medical Research

It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

1. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.

3. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

4. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

5. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

6. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.

The subjects must be volunteers and informed participants in the research project.

7. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the in-

formed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

11. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

12. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

Additional Principles For Medical Research Combined With Medical Care

1. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

2. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treat-

ment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.

3. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

4. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

5. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review. 9.10.2004

Supplement 17

WORLD MEDICAL ASSOCIATION STATEMENT ON ANIMAL USE IN BIOMEDICAL RESEARCH*

Adopted by the 41st World Medical Assembly (Hong Kong, 1989)

In September, 1989 the WMA has adopted the Statement on Animal Use in Biomedical research.

Biomedical research is essential to the health and well-being of every person in our society. Advances in biomedical research have dramatically improved the quality and prolonged the duration of life throughout the world. However, the ability of the scientific community to continue its efforts to

* The WMA official site http://www.wma.net/e/policy/a18.htm

improve personal and public health is being threatened by a movement to eliminate the use of animals in biomedical research. This movement is spearheaded by groups of radical animal rights activists, whose views are far outside mainstream public attitudes and, whose tactics range from sophisticated lobbying, fund raising, propaganda and misinformation campaigns to violent attacks on biomedical research facilities and individual scientists.

The magnitude of violent animal rights activities is staggering. In the United States alone, since 1980, animal rights groups have staged more than 29 raids on U.S. research facilities, stealing over 2,000 animals, causing more than 7 million dollars in physical damages and ruining years of scientific research in the process. Animal activist groups have engaged in similar activities in Great Britain, Western Europe, Canada and Australia. Various groups in these countries have claimed responsibility for the bombing of cars, institutions, stores, and the private homes of researchers.

Animal rights violence has had a chilling effect on the scientific community internationally. Scientists, research organizations, and universities have been intimated into altering or even terminating important research efforts, that depend on the use of animals. Laboratories have been forced to divert thousands of research dollars for the purchase of sophisticated security equipment. Young people who might otherwise pursue a career in biomedical research are turning their sights to alternative professions.

Despite the efforts of many groups striving to protect biomedical research from animal activism, the response to the animal rights movement has been fragmented, under-funded, and primarily defensive. Many groups within the biomedical community are hesitant to take a public stand about animal activism because of fear of reprisal. As a result, the research establishment has been backed into a defensive posture. Its motivations are questioned, and the need for using animals in research is repeatedly challenged.

While research involving animals is necessary to enhance the medical care of all persons, we recognize also that humane treatment of research animals must be ensured. Appropriate training for all research personnel should be prescribed and adequate veterinary care should be available. Experiments must comply with any rules or regulations promulgated to govern human handling, housing, care, treatment and transportation of animals.

International medical and scientific organizations must develop a stronger and more cohesive campaign to counter the growing threat to public health posed by animal activists. Leadership and coordination must be provided.

The World Medical Association therefore affirms the following principles:

1. Animal use in biomedical research is essential for continued medical progress.

2. The WMA Declaration of Helsinki requires that biomedical research involving human subjects should be based on animal experimentation but also requires that the welfare of animals used for research be respected.

3. Humane treatment of animals used in biomedical research is essential.

4. All research facilities should be required to comply with all guiding principles for humane treatment of animals.

5. Medical Societies should resist any attempt to deny the appropriate use of animals in biomedical research because such denial would compromise patient care.

6. Although rights to free speech should not be compromised, the anarchistic element among animal right activists should be condemned.

7. The use of threats, intimidation, violence, and personal harassment of scientists and their families should be condemned internationally.

8. A maximum coordinated effort from international law enforcement agencies should be sought to protect researchers and research facilities from activities of a terrorist nature.

Supplement 18

THE CONSTITUTION OF UKRAINE

Article 21. All people shall be free and equal in their dignity and rights. Human rights and freedoms are inalienable and inviolable.

Article 24. Citizens shall have equal constitutional rights and freedoms and shall be equal before the law.

There shall be no privileges or restrictions base on race, skin color, political, religious and other beliefs, sex, ethnical and social origin, property status, place of residence, linguistic or other characteristics.

The equality of rights for women and men is provided: by granting the women and men equal possibilities in the public-political and cultural activities, in receiving the education and professional training, in labour and fee for it; by special measures on women's labour and health protection, by the establishment of pensions privileges; by creating conditions, which enable the women to connect labour with maternity; by legal defence, financial and moral support of maternity and childhood, including the grant of paid vacations and other privileges to the pregnant women and mothers.

Article 28. Everybody has a right to respect for his/her dignity.

Nobody can be subjected to torture, cruel, inhuman or humiliating to his/her dignity conduct or punishment.

Nobody can be subjected to medical, scientific or other experiments without his/her free consent.

Article 46. Citizens have a right to social protection, which includes the right to receive social provision in the cases of complete, partial or temporal disability, loss of the bread-winner, unemployment for reasons beyond their control, old age and in other statutory cases.

This right is guaranteed by obligatory state social securities due to the insurance payments of citizens, enterprises, institutions and organizations, as well as the budgetary and other sources of public welfare; by creating a network of state, communal and private institutions for the care of the disabled.

Pensions, other types of social payments and help which are the basic source of existence must provide the standard of living, not lower the minimal living wage established by the law.

Article 49. Everybody has a right to health protection, medical care and medical insurance.

Health protection is provided by state financing of the appropriate socio-economic, medico-sanitary and health-improvement-prophylactic programs.

The state creates conditions for effective and accessible for all the citizens medical service. At the state and communal health institutions medical care is provided free of charge; the existing network of such institutions can not be shortened.

The state promotes the development of medical institutions of all kinds of ownership.

The state supports the development of physical culture and sports and provides for the sanitary-epidemic wellbeing.

Article 50. Everybody has a right to an environment that is safe for life and health, and to compensation for damages inflicted through the violation of this right.

Everyone is guaranteed a right to free access to the information on the state of environment, the quality of food stuffs and domestic articles, and also the right to its distribution. Such information can not be made secret.

Article 51. Marriage is based on the free consent of a woman and a man. Each member of a married couple has equal rights and duties in the marriage and family. Parents are under an obligation to support their children to their majority. Adult children are under an obligation to care of the disabled parents. Family, childhood, maternity and paternity are protected by the state.

Article 52. Children shall be equal in their rights irrespective of their origin, and also of being born in the wedlock or out of it.

Any violence against a child and his/her exploitation is pursued by law.

The support and education of orphaned children and children deprived of paternal care is provided by the state. The state encourages and supports the charitable activity in relation to children.

Article 68. Every person must strictly abide by the Constitution of Ukraine and the laws of Ukraine, and not to encroach upon the rights and freedoms, honour and dignity of other persons.

Ignorance of the law does not relieve from legal responsibility.

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Навчальне видання

ЗАПОРОЖАН Валерій Миколайович
АРЯЄВ Микола Леонідович

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Підп. до друку 26.05.2008. Формат 60x84/16.
Папір офсетний. Гарн. Таймс. Друк різографічний. Ум. друк. арк. 17,05.
Обл.-вид. арк. 22,0. Тираж 50. Зам. 1117.

Видано і надруковано Одеським державним медичним університетом.
65026, Одеса, Валіховський пров., 2.

Свідоцтво ДК № 668 від 13.11.2001.

Запорожан В. М.

З-33 Біоетика : підручник : пер. з укр. / В. М. Запорожан, М. Л. Аряєв. — Одеса : Одес. держ. мед. ун-т, 2008. — 288 с. — (Б-ка студента-медика). — Мова англ.

ISBN 978-966-443-006-4

У підручнику йдеться про предмет, теоретичні основи й етапи розвитку біоетики як дисципліни. Розглянуто біоетичні аспекти взаємовідношень між медичним персоналом, хворою людиною та членами її сім'ї, а також питання вмирання та смерті, репродукції людини, контролю генетичних технологій, медичних досліджень і соціальної етики медицини.

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Іл. 5. Табл.2. Бібліогр.: 38 назв.

ББК 87.75я73