

MINISTRY OF HEALTH OF UKRAINE
ZAPORIZHZHIA STATE MEDICAL UNIVERSITY
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FOUNDATIONS OF BIOETHICS AND BIOSAFETY

EDUCATIONAL MANUAL

for independent work
of students of the 1-st course
of II International Faculty

Field of study 22 «Health»
Specialty 222 «General Medicine»

Zaporizhzhia

2020

UDC 608.1/.3+614.253](075.8)
S48

*Approved at the meeting of Central Methodical Council of ZSMU
and recommended for the use in the educational process
(protocol № 1 from 01.10.2020)*

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S48 Sepetyi D. P. Foundations of Bioethics and Biosafety: Educational manual for independent work of students of the 1-st course of II International Faculty. – Zaporizhzhia: ZSMU, 2020. – 97 p.

The manual contains themes, glossary, plans, reviews of the themes, control questions and tasks for independent work in the discipline Foundations of Bioethics and Biosafety. For the students of the 1-st course of II International Faculty.

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PREFACE

The development of science and technology in the contemporary world has greatly enhanced human possibilities and, at the same time, posed a number of new ethical problems and made some traditional problems more acute. This is especially true of the scientific and technological development in the fields of biology and medicine. New biotechnologies provided physicians with means to cope with many diseases and bodily deficiencies and gave them great power over human life and death, and large responsibilities. This gives rise to the requirement that a contemporary physician should be well aware of the main bioethical problems and what is involved in them; understand alternative possibilities and attitudes with respect to these problems, reasons for and against these alternatives. The proposed course, "Foundations of Bioethics and Biosafety", purports to give basic integrated grasp of this ethical dimension of medical profession.

Because the work program of the course does not include seminar lessons, the independent work of students acquires special importance. This manual provides guidance for such a work. It covers seven themes; for every theme, students can find the plan for preparation, control questions and tasks, the glossary of key terms, and the review of the theme. This enables a student to master the theme and acquire good understanding of the corresponding problems and their possible solutions. To consolidate this knowledge and check the level of a student's mastery of the discipline, students are proposed to prepare a report (referat) and undergo testing. The list of the topics for reports and control test questions is posed at the end of this manual.

The results of the study are estimated on the two-point scale: "passed", "failed". A student receives an assessment "passed" if he/she has completed all kinds of works provided by the curriculum in the history of medicine, he/she attended all lectures according to thematic plans or made reworks of absences in proper time, and earned the total number of points from 120 to 200.

Points are counted for

- homeworks - from 70 to 112 points;
- report - from 16 to 28 points;
- final testing - from 34 to 60 points.

Conversion of points according to ECTS

| The amount of points for all types of educational activities | Mark ECTS | Rating on a national scale |
|--|-----------|--|
| 180-200 | A | passed |
| 160-179 | B | |
| 140-159 | C | |
| 130-139 | D | |
| 120-129 | E | |
| 70-119 | FX | failed, with the possibility of repeat test |
| 0-70 | F | failed, with compulsory repetition of discipline |

THEME 1. BIOETHICS: SUBJECT, TASKS, PRINCIPLES, THE HISTORY OF DEVELOPMENT, AND LEGISLATIVE FOUNDATIONS

Plan

1. Ethics as a philosophical discipline. Main ethical theories: virtue ethics, consequentialism, deontology.
2. The definition, subject and tasks of biomedical ethics
3. The history of the development of biomedical ethics
4. The legislative foundations of bioethics

Key words: morality, ethics, moral philosophy, medical ethics, bioethics, biotechnology, virtue ethics, consequentialism, utilitarianism, deontological ethics, deontology, philosophy of medicine

Control Questions

1. What is the difference between biotechnology's being interdisciplinary and multidisciplinary?
2. What advantages and disadvantages proceed from biotechnology's being interdisciplinary?
3. What do you think might be advantageous and disadvantageous about biotechnology's being multidisciplinary?
4. How do advances in biotechnology generate ethical problems?
5. What do you think might be the difference between an ethical problem and a social problem?
6. Give two examples each of (1) an ethical problem generated by biotechnology, and (2) a social problem generated by biotechnology?
7. Explain the meaning of terms 'virtue ethics', 'consequentialism', and 'deontology'.

Task

1. Make a list of actions that are now possible thanks to biotechnology but which weren't possible 100 years ago. Using your list identify at least one ethical or social problem that is generated by this action.
2. Select a biotechnology that particularly interests you. Think of the ethical and social issues you think might be generated by it. Describe them.

Recommended Reading

1. Beauchamp T. L., Childress J. F. Moral Norms // Beauchamp T. L., Childress J. F. Principles of Biomedical Ethics. – New York: Oxford University Press, 2019. – P. 1-30.
2. Bryant J., Velle L. Ethics and Bioethics // Bryant J., Velle L. Introduction to Bioethics. – Wiley-Blackwell, 2018. – P. 23-38.
3. Talbot M. Biotechnology and Bioethics: What it is All about? Ethical theories: virtue, duty and happiness // Talbot M. Bioethics. An Introduction. – Cambridge University Press, 2012. – P. 3-47.
4. Veatch R., Guidry-Grimes L. The Hippocratic Oath and Its Challengers: A Brief History // Veatch R., Guidry-Grimes L. The basics of bioethics. – London, New York: Routledge, 2019. – P. 18-36.

Review of the Topic

The definition, subject and tasks of biomedical ethics

Bioethics is an interdisciplinary field that has emerged to address normative ethical issues in medical practice, research, and policy – the moral, legal, political, and social issues raised by medicine, biomedical research, and life sciences technologies.

Translated from Greek, *bioethics* means *ethics of life*

The *object* of bioethics is life in the broadest sense

Three broad spheres of bioethics:

1) Academic bioethics - a sphere primarily focused on how theoretical and practical aspects of medicine affect considerations such as special obligations or responsibilities of clinicians, what is valuable, good, right, etc. in the biomedical context and how one might go about providing systematic accounts of such considerations.

2) Public policy and law bioethics – its concerns lies in how legal and extra-legal institutions can and should be involved in the regulation of clinical and research practices.

3) Clinical ethics - its focus is directly related to how the incorporation of bioethics into clinical practice can help to improve patient care.

Some of the most important recent advances of medical science:

- Doctors and scientists can extend and create life in more ways than ever before.
- Life-support machines help a person's heart beat and lungs breathe.
- Experimental drugs keep life-threatening illnesses like cancer and heart disease at bay for years.
- Babies are conceived in a petri dish.
- Scientists have even discovered techniques to manipulate human genes.

Benefits: less disease, longer life, less suffering

New responsibilities:

- The burden of deciding between life and death at times now rests with people.
- Resources like transplant organs and money to pay for expensive treatments are scarce.
- Machines can keep a heart beating and lungs breathing, but is that a life the patient would want to live?
- Researchers can investigate new drugs and treatments, but on whom will they be tested, and what risks will patients face?
- Who decides?

Some of the most debatable bioethical issues:

- Should life be sustained mechanically when the brain's functions have ceased?

- Should potential parents be permitted to manipulate the genetic characteristics of their embryos?
- Should society ration medical care to control costs?
- Should fetal stem cells be experimented upon in an effort to eventually palliate or cure debilitating diseases?
- the responsibilities of researchers to subjects in clinical trials;
- the proper criteria for determining when a living organism has died;
- the allocation of scarce, life-saving medical resources;
- the subsidization of pharmaceutical products for those who may, as a result of their genetic makeup, miss out on some of the benefits modern medicine has brought.

According to H. T. Engelhardt, bioethics can be considered as the third stage in the development of (modern) philosophy of medicine. On the first stage (16th-17th centuries), philosophy of medicine addressed issues of prescription and classification. On the second stage (from 18th century), the field examined how medicine justified its empirical claims. On the third stage (beginning with 1970s), bioethics emerged as a distinct field within the philosophy of medicine. This stage is characterized by the emergence of secular moral experts whom the public accepted as guides, for medical decision-making and health-care policy.¹

K. W. Wildes highlights the appropriateness of considering bioethics as a branch of social philosophy. This is due to the following points:

- the controversies in bioethics often reflect deeper social and moral issues that transcend the boundaries of medicine and ethics;
- the bioethical study of medicine demands study of society itself – the social context of the practice of medicine;
- the interconnections between the scientific norms of medicine and society's social and moral norms;

¹ Engelhardt H. T. The Ordination of Bioethicists as Secular Moral Experts. – P. 61-63.

- medicine is a social construction: definitions of key medical concepts are socially influenced;
- bioethics's grounding in social philosophy is also evident in bioethics's involvement with aspects of public authority:
- bioethics considers questions involving the social allocation of resources, and so it cannot be divorced from those contemporary questions of ethics and social philosophy that are relevant to debates over distributive justice.²

The history of the development of biomedical ethics

In the history of the development of biomedical ethics, four stages are usually distinguished:

- 1) formation of the foundations of the discipline in ancient societies;
- 2) formation of corporate medical ethics in Middle Ages;
- 3) deontological ethics of the Modern period;
- 4) the bioethical stage.

On the first stage, contributions to the development of medical ethics were made by prominent medical doctors and philosophers of India, Mesopotamia, Egypt, Greece, Rome. Medical ethics was formed together with ethics generally. Ethics is the science of morality (from Latin *moralis* - luck, customs, habits, behavior, fashion). Foundations of ethics in the ancient Greek philosophy were laid by Socrates (469-399 BC), and developed by Plato (427-347 BC) and Aristotle (384-322 BC). The foundations of the medical ethics were laid by the famous Greek physician Hippocrates (born about 460 BC; lived nearly 83 years), and the school he founded.

The most important views of Hippocrates:

- treatment should be a scientific activity based on the monitoring of the course of disease and the evaluation of the effectiveness of attempted treatments;
- medicine is to be separated from religion but not from moral sources;

² Wildes K. Bioethics as Social Philosophy

- "the love for the medical art is the love for humanity";
- the doctor must enter the patient's home with the intention of bringing good and avoiding harm and injustice.

The followers of Hippocrates formulated the famous code of medical ethics, known as the Hippocratic Oath.

The second stage, of the formation of corporate medical ethics, was connected with the emergence and spread of monotheistic religions (Judaism, Christianity, Islam, and later) and with the establishment of medical faculties of universities (X-XII centuries) and medical corporations. The bearers of medical knowledge were usually priests and monks. The main consequences of the formation of medical faculties in universities were the independence and wide spread of the profession of a physician, the growth of its prestige. Graduates of medical faculties make a "faculty promise", the content of which is close to the text of the Hippocratic Oath.

The third stage, deontological was connected with the development of modern science, and attempts to secure rational foundations for ethics. The adjective "deontological" is due to the title of an influential book published in 1834, by the British philosopher and lawyer Jeremy Bentham, "Deontology, or the science of morality". The main idea of the book is that ethics (moral estimation) should be based on the calculation of usefulness: an action is good or bad, deserves approval or censure depending on its tendency to increase or decrease the general amount of happiness in society.

The fourth stage, bioethical, is usually dated from the end of 1960-s of the beginning of 1970-s. The word "*bioethics*" was first used in 1969 by medical researcher Van Rensselaer Potter to describe his idea of studying the link between human values and biological knowledge. The bioethical stage is connected with the emergence of important new institutions. So, in 1971, André Hellegers founded the Kennedy Center for Bioethics at Georgetown University – "a university-based

locus both for theoretical reflection on issues in the field as well as for the training of the new profession of clinically engaged philosophers and ethicists”.³

In 1974, USA Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission was set the task “to identify the ethical principles which should underlie the conduct of biomedical and behavioral research with human subjects and develop guidelines that should be followed in such research.”⁴ The most important results of the work of the Commission were formulated in the document titled “The Belmont Report”. Three main principles were identified:

- the principle of respect for persons, which should underlie the guidelines for informed consent;
- the principle of beneficence, which should guide the assessment of risks and benefits;
- the principle of justice as a guidance for fair selection of subjects of experiments.

Although these principles were formulated for biomedical research, they can be applied to clinical practice as well. A short time after the Belmont Report, the members of the Commission James Childress and Tom Beauchamp made this generalization in the book *Principles of Biomedical Ethics* (1979), which has become one of the most influential works in bioethics. In the next decade, several other ethicists tried to develop a general framework of biomedical ethics on different foundations. So, Robert Veatch in the book *Theory of Medical Ethics* (1984) proposed to ground bioethics in the influential version of an ethical contract theory advanced by John Rawls. H. Tristram Engelhardt, in *Foundations of Bioethics* (1986), reworked and applied to medicine Immanuel Kant’s thesis of autonomy as the essence of the moral life; he advanced theoretically grounded

³ Engelhardt H. T. The Ordination of Bioethicists as Secular Moral Experts. – p. 78.

⁴ Jonsen A. The History of Bioethics as a Discipline. – p. 38.

arguments for the prioritization of principles, such as respect for the freedom of individuals, over consequentialist and utilitarian considerations.

K. W. Wildes explains the emergence of bioethics as due to the following main factors:

- advances in medical knowledge and technology;
- the development of large medical bureaucracies;
- the rise of moral pluralism.⁵

H. T. Engelhardt emphasized the importance of such factors as

- the deprofessionalization of medicine;
- the secularization of society;
- a socially perceived need for guidance in questions of medical research and health care.⁶

To understand the specificity of bioethics, as compared with earlier stages of medical ethics (traditional medical ethics, coming down to Hippocrates), the following comparative table can be useful

| Traditional medical ethics | Bioethics |
|--|---|
| two main sources of moral guidance: 1) the tradition of professional physician ethics; 2) the teachings of the dominant theological ethics | the two traditional sources were no longer able to guide medicine because of “moral pluralism”: people not only hold different moral views on topics (e.g., abortion), but work out of different moral frameworks and with different moral methodologies. |
| primarily concerned with the conduct of <i>physicians</i> ; the ethics of the guild | the realization of the important roles of nonphysicians in the ethical choices present in medicine |
| paternalistic model of the | procedures like informed consent |

⁵ Wildes K. Bioethics as Social Philosophy

⁶ Engelhardt H. T. The Ordination of Bioethicists as Secular Moral Experts

| | |
|--|--|
| relationship between the physician and the patient | have come to play a central role in both clinical and research ethics |
| A key part of the classical notion of a profession was that professions had distinctive moral dimensions. The importance of the notion of an internal ethics of physicians | A wide range of views among physicians – on issues ranging from abortion to physician-assisted suicide and the economic structures underlying medicine – about what is or is not appropriate behavior. It becomes more and more difficult to sustain claims based on an internal morality of medicine |
| the prominence of theologians | Bioethics “pushed religion aside”. As bioethics became a form of “public” discourse, it moved to the more "neutral" languages of philosophy and law and away from the "closed" languages of the medical profession and theological discourse. |

The legislative foundations of bioethics

Bioethics is based on the foundation of human rights formulated in the General Declaration of Human Rights (1948) and the European Convention for the Protection of Human Rights and Fundamental Freedoms (1950). More specifically, bioethical issues are regulated by such international documents as

- Nuremberg Code (1947);
- The Declaration of Helsinki;
- The Declaration of Geneva (The International Medical Oath);
- International Code of Medical ethics (World Medical Association, 1949)

- The Convention on Human Rights and Biomedicine (Bioethics Convention), approved by the Committee of Ministers of the Council of Europe in 1996;
- General Declaration of the Human Genome and Human Rights (UN, UNESCO, 1997).

In Ukraine, important bioethical issues are regulated by The Constitution of Ukraine, the Ethical Code of Ukrainian Doctor (approved by the Decision of the Ukrainian Medical Council Protocol, January 27, 2006), Foundations of the Law of Ukraine on Health Care, and other normative documents.

Glossary

Morality (from Latin: *moralitas*, lit. 'manner, character, proper behavior') is the differentiation of intentions, decisions and actions between those that are distinguished as proper and those that are improper. Morality can be a body of standards or principles derived from a code of conduct from a particular philosophy, religion or culture, or it can derive from a standard that a person believes should be universal.

Ethics or **moral philosophy** is a branch of philosophy that involves systematizing, defending, and recommending concepts of right and wrong conduct.

Medical ethics is a system of moral principles that apply values to the practice of clinical medicine and in scientific research. Medical ethics is based on a set of values that professionals can refer to in the case of any confusion or conflict. These values include the respect for autonomy, non-maleficence, beneficence, and justice.

Bioethics is the study of the ethical and social issues generated by biotechnology.

Biotechnology is the application of science and technology to living organisms and their parts, or to products and models of living organisms, in the hope of producing understanding, goods or services.

Virtue ethics are normative ethical theories which emphasize virtues of mind, character and sense of honesty. Virtue ethicists discuss the nature and

definition of virtues and other related problems that focus on the consequences of action. These include how virtues are acquired, how they are applied in various real life contexts, and whether they are rooted in a universal human nature or in a plurality of cultures.

Consequentialism is the class of normative ethical theories holding that the consequences of one's conduct are the ultimate basis for any judgment about the rightness or wrongness of that conduct. Thus, from a consequentialist standpoint, a morally right act (or omission from acting) is one that will produce a good outcome, or consequence.

Utilitarianism is a family of consequentialist ethical theories that promotes actions that maximize happiness and well-being for the affected individuals.

Deontological ethics or *deontology* (from Greek δέον, deon, "obligation, duty") is the normative ethical theory that the morality of an action should be based on whether that action itself is right or wrong under a series of rules, rather than based on the consequences of the action. It is sometimes described as duty-, obligation- or rule-based ethics. Deontological ethics is commonly contrasted to consequentialism, virtue ethics, and pragmatic ethics. In this terminology, action is more important than the consequences.

Philosophy of medicine is a branch of philosophy that explores issues in theory, research, and practice within the field of health sciences.

THEME 2. BIOETHICAL FOUNDATIONS OF THE PROFESSIONAL ACTIVITY OF A PHYSICIAN, AND THE RELATIONSHIP BETWEEN MEDICAL STAFF, THE PATIENT AND HIS FAMILY

Plan

1. Bioethical foundations of the professional activity of a physician
2. Models of the relations between a physician and a patient
3. Bioethical aspects of the relationship between medical staff, the patient and his family

Key words: informed consent, confidentiality, medical secrecy, paternalistic model, engineering model, collegial model, contract model, psychotype.

Control Questions

1. What are the conditions for restricting a patient's right to privacy?
2. How is the patient's right for confidentiality ensured *de jure* and *de facto*?
3. What does the principle of informed consent mean?
4. What is included in the doctor-patient interaction system?
5. Give characterisation of paternalistic, engineering, contractual and collegial models of doctor-patient relationships.
6. Describe the main patients' psychotypes.
7. Which of the patients' psychotypes is the most problematic and why?

Task

Think of the relative advantages and disadvantages of different models of the relationship between a physician and a patient. Which model do you find the most optimal to date? Explain why do you think so in the form of an essay for 2-3 pages.

Recommended Reading

1. Beauchamp T. L., Childress J. F. Professional – Patient Relationships // Beauchamp T. L., Childress J. F. Principles of Biomedical Ethics. – New York: Oxford University Press, 2019. – P. 327-384.

2. Childress J. Who should decide? Paternalism in health care. – Oxford University Press, 1982. – 264 p.
3. Zaporozhan V.M., Aryayev M.L. Bioethical Bases of a Doctor`s Professional Activity // Zaporozhan V.M., Aryayev M.L. Bioethics. – Odessa: Odessa State Medical University, 2008. – P. 63-111.
4. Veatch R., Guidry-Grimes L. Principle- based Approaches to Moral Problems in Bioethics // Veatch R., Guidry-Grimes L. The basics of bioethics. – London, New York: Routledge, 2019. – P. 63-79.

Review of the Topic:

Bioethical foundations of the professional activity of a physician

Ethical and philosophical foundations of Hippocratic medicine:

- Do no harm!
- physician as a helper of nature (hygienic and dietary rules);
- the sanctity of life.

“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.”

This fragment explicitly states two important principles that a physician should follow in his/her relationship with a patient: the principle of help and support and the principle of non-harming.

World Medical Association issued a number of important documents that formulate basic ethical principles of medical ethics, such as the Declaration of Geneva (1948), the International Code of Medical Ethics (1949, adopted by the 3th General Assembly of the WMA).

In 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research had issued the Belmont report, in which the principles of respect for persons, beneficence, and justice were identified as the foundation of the ethics of biomedical research. This framework was developed and applied to medical practice in general by T.L. Beauchamp and J.F. Childress in

the book “The Principles of Biomedical Ethics” (1979). It distinguishes four basic ethical principles in medicine:

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).

Recent transformation in medical ethics: from the ethics where the dominant principle is that a physician should do what he judges to be the best for the health of the patient (paternalistic attitude) to the ethics in which *the principle of respect for the patient’s autonomy* is supreme.

The respect for the patient’s autonomy involves

- patients’ being informed;
- knowing something of the physician’s values;
- being assured the physician is acting for their best interests;
- retaining veto power over suggested treatments;
- enjoying a variable degree of freedom depending on personal values.⁷

Limitations to the principle of the patient’s autonomy

- 1) immaturity, mental disorder, etc.;
- 2) conflict with a physician’s autonomy (his/her human or professional values);
- 3) danger for other people (for example, the refusal to be vaccinated).

The Declaration on the Promotion of Patients’ Rights in Europe (Amsterdam, 1994)

⁷ Schneider C. The Practice of Autonomy: Patients, Doctors, and Medical Decisions

- the principle of veracity: the actions or rules are morally right, if they are directed at granting truthful information and have a goal of avoiding dishonesty in mutual relations;
- the principle of informed consent: a competent adult patient should not be exposed to medical interference without his/her informed and voluntarily consent; it aims at choices that are optimal not only from the medical point of view but also from the point of view of the person's values.

Key aspects of informed consent:

- 1) A special procedure of receiving the patient's or examinee's voluntarily consent.
- 2) Adequate information about
 - the aims of the planned interference;
 - its duration;
 - expected positive consequences for the patient;
 - possible unpleasant sensations, risk for life, physical and/or sociopsychological well-being;
 - the existence of alternative treatment methods and their comparative efficiency;
 - the rights of the patients or examinees and the ways of their protection.

The Constitution of Ukraine, Chapter 2, article 28:

“Nobody can be subjected to medical, scientific or other experiments without his/her voluntarily consent”.

The principle of confidentiality. The information about a patient that is given to the doctor or obtained as a result of medical investigations can not be passed to a third person without this patient's permission. 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.

Models of the relations between a physician and a patient

J. Childress (1982), to describe different types of physician-patient relationship, use metaphors: parent-child, partners, contractors, technician-client, friends. Accordingly, 5 basic models of the relationship in health care can be distinguished: paternalistic (from the *Latin* pater - the father), collegial, contractual, friendly, technical.

Paternalistic model is based on a centuries-old tradition of medical practice. The center of decision-making is a medical professional, in particular, a physician who possesses authority within an asymmetric and hierarchical relationship with the patient (analogy with that of a pastor and parishioners, parents and children).

Collegial (partnership) model:

- opportunities to realize the values of an autonomous personality;
- partnership of healthcare professionals and their patients on the foundation of the recognition of the value of health;
- the equality of both parties in the interpretation of these values, including health, along with the respect for the personal autonomy of all parties;

The prototype of the model is the "adult - adult" relationship.

Contractual model: medical professionals should make a series of specific contracts with their patients. It often allows to achieve the best compromise between the ideals of partnership with the emphasis on equality and autonomy and the realities of medical practice, where mutual trust cannot be guaranteed.

Friendship model is based on the view that a good physician is always a friend to a particular patient and all patients. The model implies that the patient trusts the physician, and the friendship of the physician is manifested in the desire to provide effective technical assistance and goodwill. The model makes its moral focus on achieving equality, autonomy and the rights of both parties.

Technical (engineering) model is patterned on the relationship between the technician (or engineer) and the client. The body of the patient is compared with the mechanism, and the disease is interpreted as its disorder, which the physician, as an engineer or technician, have to eliminate. The physician offers or provides

technical services to the patient as a consumer. The treatment process reduces to manipulations with the patient's body.

Bioethical aspects of the relationship between medical staff, the patient and his family

In the bioethical context, the relationship between medical staff, the patient and his family are considered in the light of diverse economic, political, cultural and transcultural relations. The main concern is the interests of the patient as a consumer of medical services and society as a whole, not the interests of the medical corporation. However, medical employees are recognized to have not only responsibilities but natural rights as well.

A special role in the relationship between patients and medical staff belongs to *nurses*, who face the full range of moral problems encountered by physicians and, besides, additional problems arising from her professional role. Like a physician, a nurse sometimes is forced to choose: either to do what she thinks will promote the well-being of the patient, or to act on the basis of the esteem for the choice of the patient. Like the Hippocratic Oath for physicians, there is a similar ethical code for nurses, called The Florence Nightingale Pledge:

“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.”

In the Pledge, we see a number of ethical principles that we have already met when discussing the ethical principles of the relationship between a physician

and a patient: the principle of help and support, the principle of non-harming, the principle of confidentiality.

The role of the family. The physician should not only be a good diagnosticist and therapist, but also have training in psychology, pedagogy, sociology and cultural issues. It is necessary to help family members to adjust to the care of the patient, to properly orient them in matters of treatment. From the beginning of the disease, the patient plays a new role in the family - the "role of the patient", which implies certain rights and obligations.

The tasks of the physician in his/her work with the patient's family:

- to form a correct view of the disease;
- to help family members change their lives under new conditions, stimulate adaptation reactions;
- to promote the involvement of the patient in the life of the family and prevent misconduct.

Glossary

Informed consent is a process for getting permission before conducting a healthcare intervention on a person, or for disclosing personal information. A health care provider may ask a patient to consent to receive therapy before providing it, or a clinical researcher may ask a research participant before enrolling that person into a clinical trial. Informed consent is collected according to guidelines from the fields of medical ethics and research ethics.

Confidentiality (privacy) - an attitude toward information that forbids making it public.

Medical secrecy - the obligation of medical professionals and other persons who have got information about a person's disease, medical examination, intimate and family aspects in the process of performing their professional or official duties not to disclose this information except for cases envisaged by the legislation.

Paternalistic model implies that the physician, after careful examination of the patient's condition, establishes the most appropriate treatment for each specific

situation, aimed at full recovery. The last word in the choice of treatment options remains with the physician.

Engineering model: the patient is perceived by the doctor as an impersonal mechanism. Treatment reduces to manipulations with the patient's body.

Collegial model: the patient is considered as equal in his/her interaction with the physician. In order to play one's role, the patient must obtain from the physician sufficient information about his/her health status, treatment options, prognosis, possible complications, etc. In this case, the patient can participate in the elaboration of specific decisions regarding the treatment; he/she exercises the inherent right of the individual for the freedom of choice.

Contract model: interaction between a physician and a patient is based on a contract. Patients enter into a health care contract with a hospital or through an insurance company. Each party to such an agreement has its obligations and each achieves its benefits.

Psychological types (psychotypes) - a characteristic of a person in terms of psychology. Because there are many psychological schools, there are different classifications of psychological types. Any human psychotype is a generalization, an attempt to group similar qualities that are often observed together, character traits, temperament features, behavior and other traits of personality.

THEME 3. THE PRINCIPLES AND ETHICAL PROBLEMS OF BIOMEDICAL RESEARCH

Plan

1. The main ethical principles of biomedical research. The Nuremberg Code and the Declaration of Helsinki.
2. Ethical principles of testing with animals.
3. The principles of clinical research.
4. Ethical committees, their functions and impact

Key words: placebo, experimental units, treatment group, double-blind study, randomization.

Control Questions

1. What are the main international documents that regulate scientific research in medicine?
2. What is the content of the Nuremberg Code and its significance for the regulation of biomedical experiments?
3. What are the ethical principles of animal research called the "three R"?
4. What legislative documents regulate medical research in Ukraine?
5. What legislative documents regulate medical research in your country?
6. What are Ethical committees? When and for what purpose they were established?

Task

Write an essay (1-2 pages) on how the principles of biomedical ethics influence experimental research in the world and in your country.

Recommended Reading

1. Beauchamp T. L., Childress J. F. The Distinction between Clinical Ethics and Research Ethics // Beauchamp T. L., Childress J. F. Principles of Biomedical Ethics. – New York: Oxford University Press, 2019. – P. 360-370.

2. Bryant J., Velle L. Humans and Hon-Human Animals // Bryant J., Velle L. Introduction to Bioethics. – Wiley-Blackwell, 2018. – P. 265-284.
3. Bunge M. Trial // Bunge M. Medical Philosophy. Conceptual Issues in Medicine. – World Scientific, 2013. – P. 129-150.
4. Veatch R., Guidry-Grimes L. Social Ethics of Medicine: Allocating Resources, Health Insurance, Transplantation, and Human Subjects Research // Veatch R., Guidry-Grimes L. The basics of bioethics. – London, New York: Routledge, 2019. – P. 234-268.

Review of the Topic

The main ethical principles of biomedical research. The Nuremberg Code and the Declaration of Helsinki

During the last two centuries, medicine greatly improved and attained the powers to deal successfully with great many deceases and health problems that were incurable before. To a great extent, this was due to the change in the method of the evaluation of the efficiency of medicines. Two or more centuries ago, it was based on individual cases of medical practice, which didn't provide the sufficient data for the objective reliable evaluation. The mistake *post hoc ergo propter hoc*, when the fact that an event B (such as patient's health restoration) happened after and event A (such as taking a certain medicine) was taken as the indication that B happened because of A (that the medicine at issue is efficient for treatment of this decease) was rife, and really efficient medicines rare. From 19th century, and especially in 20th century, much more reliable methods – systematic scientific research in laboratories and clinics – were widely introduced.

Besides beneficent consequences for science and medicine, biomedical research is connected with ethical problems and requires adequate regulation. The importance of this was made obvious by Nazi's crimes during the 2nd World War, which included biomedical research with Nazi's victims in concentration camps – awful sufferings and deaths of human beings on which theses experiments were held by German scientists. After the War, there was the great trial in Nuremberg

and a hot discussion about biomedical research that resulted in an important document, the Nuremberg Code.

The Nuremberg Code (1947) is a set of research principles focused on the rights of human participants rather than the interests of scientists. The central principle was that in all biomedical research with human participants, their voluntary consent is absolutely essential. Other important provisions were:

- the research should be expected to bring fruitful results for the good of society that outweigh the risks involved;
- all unnecessary physical and mental sufferings should be avoided;
- no research should be conducted where there is a reason to believe that death or disability injury will occur;
- the degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved.

The principles of the Nuremberg Code were developed in the Declaration of Helsinki, first adopted in 1964, and later many times readopted with revisions and improvements. This document is widely considered as the main international normative document that regulates biomedical research with human participants.

The Declaration

- emphasizes that “The well-being of the human subject should take precedence over the interests of science and society”;
- reaffirms the principle of informed consent and requires that the consent should be in writing;
- warns against participation, if a potential participant is in dependent relationship with researcher;
- stipulates limitations on the use of placebo;
- requires that participants should be expected to have medical benefit from research.

Ethical principles of animal research

The Three R's (3R's) are guiding principles for more ethical use of animals in testing:

- ✓ Replacement
- ✓ Reduction
- ✓ Refinement

The aim is to improve animal welfare and scientific quality where the use of animals can not be avoided. The principles are implemented in many testing establishments worldwide and have been adopted by various pieces of legislation and regulations.

Replacement – preference for non-animal methods over animal methods whenever it is possible to achieve the same scientific aims.

Reduction – preference for methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.

Refinement – preference for methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used.

The guiding principles of the biomedical research with human participants

Phases of Clinical Trials:

1) Researchers test a small group of twenty to eighty healthy patients to evaluate a drug's safety, set dose ranges, and determine if there are any side effects.

2) A larger group of one hundred to three hundred people receive the drug. These participants generally have the disease the treatment targets. During this phase, researchers evaluate how effective the treatment is and continue to assess its safety. If a treatment appears to be acceptably safe and effective, it moves on to Phase 3 testing.

3) Research involves even greater numbers of people with the disease, usually around one thousand to three thousand subjects. Testing in this phase

monitors effectiveness, safety, and side effects. It also compares the treatment with any existing treatments for the disease. As more people are tested over longer periods of time, researchers might discover rare side effects.

Phases 1-3 are the condition for a potential treatment to be approved (licensed) by responsible state institutions.

4) Trials collect information about long-term effects and usage (often occurs after the treatment is approved for general use).

Mario Bunge on the degrees of the excellence of experiments. There standards: silver, golden, platinum.

“Silver standard”. It is not enough to check what happens after the stimulus is applied; it is also necessary to check what happens with the organism when the stimulus is *not* applied. Any biomedical experiment involves *two groups of organisms: experimental and control.*

“Golden standard” (Randomized Clinical Trial): *randomized, placebo controlled, double-blind* clinical trial.

“Platinum standard” = “Golden standard” +

the explicit formulation of the mechanism of action

Basic ethical principles of biomedical research, as formulated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the Belmont Report:

| <i>Principle</i> | <i>applies to</i> | <i>Guidelines for</i> |
|---------------------|-------------------|----------------------------|
| Respect for Persons | | Informed Consent |
| Beneficence | | Risk/Benefit Assessment |
| Justice | | Fair Selection of Subjects |

Assessing Risk and Protecting Patients. It is critical for researchers to explain all known risks before the trial. If a new risk emerges during the trial, the researchers should inform all participants.

Eligibility requirements are aimed to exclude people who have a greater risk of being harmed in the trial. They include age, sex, type and stage of disease, previous treatment history, and general medical condition. However, this gives rise

to the problem of “compassionate use” policy for terminal patients that do not meet formal eligibility requirement but for whom experimental drugs are the last hope.

Glossary

A *placebo* (/pləˈsiːboʊ / plə-SEE-boh) is an inert substance or treatment which is designed to have no therapeutic value. Common placebos include inert tablets (like sugar pills), inert injections (like saline), sham surgery, and other procedures.

In the design of experiments, treatments are applied to *experimental units* in a *treatment group*. In comparative experiments, members of a *control group* receive a standard treatment, a placebo, or no treatment at all. A placebo control group can be used to support a double-blind study.

A *double-blind study* is one in which some subjects are given an ineffective treatment (in medical studies typically a sugar pill) to minimize differences in the experiences of subjects in the different groups; this is done in a way that ensures no participant in the experiment (subject or experimenter) knows to which group each subject belongs. In such cases, a third, non-treatment control group can be used to measure the placebo effect directly, as the difference between the responses of placebo subjects and untreated subjects, perhaps paired by age group or other factors (such as being twins).

Randomization: For the conclusions drawn from the results of an experiment to have validity, it is essential that the items or patients assigned to treatment and control groups be representative of the same population. In some experiments, such as many in agriculture or psychology, this can be achieved by randomly assigning items from a common population to one of the treatment and control groups.

THEME 4. BIOETHICAL ISSUES OF NEW BIOMEDICAL TECHNOLOGIES: MEDICAL GENETICS, GENETIC ENGINEERING AND REPRODUCTIVE TECHNOLOGIES

Plan

1. The new medical technologies and the problems of bioethics.
2. The problem of the rights of embryos and abortion.
3. Bioethical problems of new reproductive technologies.
4. Bioethical problems of genetic engineering
5. Bioethical problems of cloning and stem cell research.

Key words: embryo, abortion, assisted reproductive technology (ART), in vitro fertilisation (IVF), egg donation, surrogacy, genetic engineering, genetic modification, genetic manipulation, somatic cell nuclear transfer (SCNT), cloning, reproductive cloning, therapeutic cloning.

Control Questions

1. Do we have the right to life from conception? If not when do we acquire the right to life? What are main views on this issue and arguments of their supporters?
2. What are main moral issues of egg donation and surrogacy?
3. Think of the ways in which governments might allow for the right of a child to a decent childhood consistently with recognising adults' rights to found a family?
4. Do you think that therapeutic cloning is morally acceptable? What arguments *pro* and *cons* do you know?
5. Why will clones always have 'confused and ambiguous' family relationships? Is the fact that clones will always have confused and ambiguous family relationships reason to believe that reproductive cloning should be banned?
6. Do you think that reproductive cloning will ever be morally acceptable? Why do you think so?

Task

1. Find out more about why the Warnock Committee decided that therapeutic cloning is morally acceptable until the 14th day:

<http://www.publications.parliament.uk/pa/cm200607/cmselect/cmsctech/272/27205.htm>

Make a summary (1-2 pages).

2. Read this debate on cloning between two scientists on Online Newshour: <http://www.pbs.org/newshour/health/cloning.html>

Make a summary (1-2 pages).

Recommended Reading

1. Bryant J., Velle L. Life Before Birth // Bryant J., Velle L. Introduction to Bioethics. – Wiley-Blackwell, 2018. – P. 41-82.
2. Mooney C. Genetic Testing and Engineering. Stem Cell Research and Cloning // Mooney K. Bioethics. – Lucent Books, 2009. – P. 66-92.
3. Talbot M. Cloning. Reproduction // Talbot M. Bioethics. An Introduction. – Cambridge University Press, 2012. – P. 93-202.
4. Veatch R., Guidry-Grimes L. Reproductive Choice and Advancing Technologies: Ethical Challenges in the Creation of Humans // Veatch R., Guidry-Grimes L. The basics of bioethics. – London, New York: Routledge, 2019. – P. 216-233.

Review of the Topic

The new medical technologies and the problems of bioethics

Common characteristics of the most innovative developments in biomedicine:

- The aspiration to achieve the most fundamental control over bioprocesses and biostructures, on the molecular level.
- Aim at the creation of radically new states, processes, structures, objects, etc., which are anomalous from the point of view of natural biological regularities and deeply artificial.

- These developments already have (and will exert in the future) a great impact on morality and value systems, stimulate a revision of traditional notions and social norms.

The main bioethical issues due to these developments concern:

- human genetics: human genome, biotechnology and gene therapy, cloning and stem cells;
- human procreation: human sexuality, natural reproduction, artificial insemination, natural regulation of conception and contraception, sterilization;
- embryo: human embryo, abortion, prenatal diagnosis, operations on human embryos;
- the final phase of human life: pain and euthanasia, abusive therapy, palliative evaluation, brain death and organ transplantation;
- use of transgenic plants for food purposes.

Bioethical problems of new reproductive technologies

Great scientific advances concerned with reproduction, procedures such as in vitro fertilization (IVF) and surrogacy allow childless individuals to become parents. However, these procedures raise objections, such as that medical intervention is moving too close to “playing God”, and a number of new bioethical questions, such as:

- When does life begin?
- When egg donors and surrogates are involved, who is the rightful parent?
- Does everyone have the right to become a parent no matter their age or personal situation?
- Who should decide?

Assisted reproductive technology (ART) means all fertility treatments in which both eggs and sperm are handled. It involves surgical removal of eggs from a woman’s ovaries, combining them with sperm in the laboratory, returning them to the woman’s body or donating them to another woman. Such technologies are *in vitro* fertilization (IVF), egg donation and surrogacy. At first, ART helped married

women who could not conceive naturally because of fallopian tube blockages. Later, the range of people interested in ART widened: it includes healthy couples who wanted to avoid a genetic disease such as cystic fibrosis or hemophilia, and opens a controversial door to parenthood for old women, single mothers, and same-sex partners.

Ethical problems raised by ART:

- ART research and procedures destroy and endanger human embryos, whose moral status and the right to live is a matter of heated bioethical argument. In a typical treatment cycle, doctors remove and fertilize several eggs. Of the embryos that develop, they select a few to implant. What happens to the others?

Options:

- destroyed,
 - made them available for research,
 - donated to another infertile couple,
 - frozen indefinitely.
- ART is very expensive and usually accessible only for rich people.

In vitro fertilization (IVF). In 1978, first healthy child born as a result of *in vitro* fertilization. Early success rates were low, but they improved over time. By 2005, 35 percent of IVF cycles resulted in a live birth.

Egg donation. Egg donation raise the following main criticisms:

- Infertile couples can search egg donation databases by race, height, eye color, blood type, and education. Sperm banks provide the same opportunity for selecting a future child's characteristics. Eggs from smart, pretty women are in the greatest demand and carry the highest price. Critics fear this trend demonstrates how donor databases encourage couples to select desirable traits for their child. They believe favoring attractive and intelligent donors is *a step closer to eugenics*, the practice of encouraging reproduction in people with desirable traits.
- The price of an egg is too high. Typically, donors receive several thousand dollars for their eggs. With eggs in short supply, the price for donation continues

to increase. Some people believe selling eggs is unethical. They believe eggs should be treated like hearts and kidneys and donated freely through a national donor system. The donors disagree.

Surrogacy. If a woman is unable to carry a child in her body, doctors can use ART to place an embryo in a surrogate mother's uterus. The embryo can be created from the prospective parents' egg and sperm. In this case the child is not genetically related to the surrogate mother.

Surrogacy removes natural limits of the age of mothers. Naturally, the elder women is, the less likely is that she can become mother. With surrogacy, a child can be born by the surrogacy mother and then is given to the genetic mother, with no age limitations. So, the Romanian woman Adriana Iliescu became mother at the age sixty-six, the oldest on record. This raises a new ethical questions: How old is too old for parenthood? Is it fair to bring a child into the world with parents who will be in their seventies and eighties when the child enters high school? In England doctors refused to treat a woman in her fifties, claiming she was too old for the stress of motherhood. As The British secretary of health explained, "There are deep ethical considerations, and the child's welfare must be considered. A child has a right to a suitable home."⁸

With all ethical questions raised by ART, the problem of decision-making is burning. Who should decide, and on which rules and considerations should guide such decisions? Without any substantial governmental regulation, doctors decide every day which families and children they will create and which they will not. As Applegarth points out, the decision-making requires answering difficult questions and balancing interests of a number of people: "Who is our patient? Is it the two people sitting in front of me? The child potentially created? The donor of the gamete? We have to consider all of these people when we're making these decisions."⁹

⁸ Quot. in Mooney K. Bioethics. – p. 21.

⁹ Quot. in Mooney K. Bioethics. – p. 22.

Bioethical problems of medical genetics and genetic engineering

Medical genetics – the field of medicine, the science that studies heredity and variability in different populations of people, the manifestation and development of normal and pathological features, the dependence of diseases on genetic or epigenetic abnormalities. The task of medical genetics is to identify, study, prevent and treat hereditary diseases, to develop ways of preventing the impact of negative environmental factors on human heredity.

Moral problems of medical genetics:

- the morality of diagnosing of a pathological condition of a person in the absence of effective methods of its treatment;
- the moral responsibility of mankind and society for the health not only of people that live now but also of future generations;
- keeping medical secrets, the confidentiality of genetic information;
- voluntary genetic testing of individuals and screening of the population;
- the availability of medical and genetic care for different social strata;
- moral problems of eugenics – the science that studies and develops ways and methods of active influence on the evolution of mankind, the improvement of its nature;
- moral problems of gene therapy, etc.

The Human Genome Project. In 1990, a massive international project to better understand human genes was started. By 2003, the Human Genome Project mapped the complete set of human DNA and identified the genes contained. More than fourteen hundred disease genes were identified. Part of the project was the Ethical, Legal and Social Implications (ELSI) program - the world's largest bioethics program. Some issues the program studied:

- Who should have access to personal genetic information, and how will it be used?
- How does personal genetic information affect an individual and society's perceptions of that individual?
- Should testing be performed when no treatment is available?

- Should parents have the right to have their minor children tested for adult-onset diseases?
- Where is the line between medical treatment and enhancement?

Genetic Testing is used to diagnose disease or identify the patient as a carrier of the genetic disease, to assess a person's risk of getting certain diseases. There are gene tests for more than thirteen hundred diseases, with many more in development. After testing positive, patients have a better understanding of their risk of getting the disease. As a result, they may decide to alter their diet and lifestyle to reduce other risk factors. They may be more diligent about medical exams and paying attention to warning symptoms. They may also decide to undergo aggressive preventative treatment.

Privacy concerns: genetic test results could cause social embarrassment or discrimination. Insurance companies can raise premiums or refuse to cover individuals who test positive for expensive diseases. Knowing genetic test results, employers might not hire a candidate who will have future health problems, costing the company time and money. Even current employees worry their jobs may be at risk if employers learn they have tested positive for a disease that will require time off and expensive treatments.

Preimplantation Genetic Diagnosis (PGD): In case of *in vitro* fertilization, genetic testing for an embryo before it is implanted in the uterus. This allows screening out embryos with positive results. Usually, this is used for screening for abnormal chromosomes that may lead to miscarriage, chromosome disorders such as Down syndrome, and genetic diseases like cystic fibrosis. However, the wider and more trouble-raising use is possible – to select characteristics based on preference. Already, it is possible to test embryos for inherited deafness or a predisposition to arthritis or obesity. Genetic tests can easily be used to select a baby's sex.

Some ethical problems with PGD:

- PGD is not infallible.

- At what point are we engaging in eugenics and not accepting the normal diversity within a population?
- In the United States, PGD is not regulated, so the decisions on what testing is appropriate and ethical are made by doctors and their patients.
- The high cost of PGD may be a barrier to some families. If only the wealthy can afford to screen out genetic disability and disease, some fear PGD may be the first step toward a genetic class divide. The wealthy become genetically healthier, while the poor are left to deal with disease and disability.

Genetic engineering – a complex of techniques aimed at transferring some kinds of genetic information into the structure of cells of a living creature.

Using gene therapy for treatment. Somatic gene therapy attempts to treat a specific disease by replacing defective or missing genes. To deliver the normal DNA into a patient's cells, scientists use viruses as the vehicle, which can produce negative (dangerous) side-effect. An outstanding example is treatment of severe combined immune disorder (SCID).

In 2000, French scientists reported a breakthrough in a study of infants with SCID. They took bone marrow cells from each child in the study, and added viruses to carry healthy immune system genes to these cells. Then they injected the modified cells back into the patients' bone marrow. The virus copied the new healthy genes in the patients. Within three months, the infants were home, living like normal children. Within ten months, doctors declared their immune systems completely normal. Despite their success, unintended consequences arose three years later. Three of the ten infants developed leukemia, and one died. That happened because the viruses that were used to deliver healthy genes could trigger cancer if they lodged in a patient's DNA near a cancer-causing gene.

Stem Cell Research and Cloning

Reproductive cloning. In 1997, there was the first case of cloned mammal, sheep named Dolly. Dolly was the exact DNA replica of the first ewe, from whose genetic material she was created. In addition, her birth occurred without the

involvement of a male parent. This complex procedure is called reproductive cloning.

The cloning of Dolly, a mammal, indicated that human beings can be cloned as well. This gave rise to the debate about the permissibility of human cloning. In reaction to this debate, ethics councils and legislatures around the world condemned the use of cloning to produce a human child. This attitude was supported by the United Nations. In 2005, UN backed a worldwide ban on all forms of human cloning.

One reason why human cloning is recognized impermissible is that it involves experiments with and destruction of human embryos. As William B. Hurlbut, a Stanford University ethicist, points out, “A decent society doesn’t build the foundations of its biomedical science on the creation and destruction of human embryos.”

Therapeutic cloning. Cloning can be used not for reproduction but in therapeutic purposes. In this case, the embryo is not grown into a baby but is instead used to harvest stem cells. Stem cells have the ability to renew themselves through cell division and can become, or differentiate into, a range of specialized cell types. Scientists envision a future where they would be able to grow these stem cells into other tissues and organs, which could then be transplanted into patients.

The expected possibilities of therapeutic cloning:

- cloned brain cells would treat Parkinson’s disease, and new pancreatic cells would treat diabetes;
- the use of organs cloned from a patient’s own cells would eliminate the needless deaths of people waiting on organ transplant lists;
- organ rejection would no longer be a problem for transplant patients, eliminating the need for a lifetime of expensive antirejection drugs.

There are two main types of stem cells - *adult stem cells*, found in adult tissue, and *embryonic stem cells*. Their use in therapeutic purposes has comparative

advantages and disadvantages and, in case of *embryonic stem cells*, raises hot ethical debates.

Adult stem cells:

- help to repair the body and replenish normal turnover of blood, skin, or intestinal cells;
- are limited in the range of cells they can become;
- have been used successfully to treat leukemia and other bone and blood cancers;
- no embryos are destroyed and donors knowingly give consent;
- no ethical problems with the use in research and therapies.

Embryonic stem cells:

- do not have the limitations of adult stem cells;
- the unique ability to become any one of the cell types in the human body (pluripotency), which allows the cells to develop into virtually any type of tissue or organ in the human body;
- embryos are used and destroyed, and so the problem of the ethical permissibility arises.

The stem cell debates. In 1998, James Thomson at the University of Wisconsin became the first scientist to remove stem cells successfully from a human embryo. The process destroyed the embryo. Contemporary technologies of the extraction of embryonic stem cells also involve destruction of embryos. This is the reason for a hot ethical debate: whether such research and use of human embryos is permissible. Supporters believe that stem cell research brought hope to the millions of people living with and dying of serious diseases. Opponents protest against the destruction of an embryo. Pope John Paul II described the Catholic Church's opposition to stem cell research by writing, "Human embryos obtained *in vitro* are human beings and are subjects with rights; their dignity and right to life must be respected must be respected from the first moment of their existence."¹⁰

¹⁰ Quot. in Mooney K. Bioethics. – p. 89.

Critics of stem cell research also opposed the creation of embryos specially for research use.

A partial solution of the problem can be provided by a new technology introduced in 2007. Researchers discovered a way to take adult skin cells and regress the cells back to an embryonic state. The reprogrammed adult cells, called *induced pluripotent stem cells*, or IPS cells, seemed to offer the same promise of embryonic stem cells without making or destroying human embryos. They provided scientists a way to produce genetically matched cells without cloning or egg donation. However, the use of induced pluripotent stem cells have serious limitations:

1) IPS cells are still very preliminary, and they will need a lot of work before you can say that they would be better or equivalent to embryonic stem cells.

2) The risk of cancer: reprogramming the adult cells involves viruses that sometimes turn off tumor-suppressing genes, causing a cancer to grow out of control, and a gene known to increase the risk of cancer.

Another partial solution of the problem can be the use of stem cells extracted from cord blood. Cord blood is the blood remaining in the umbilical cord and placenta after birth; it is a rich source of stem cells. These stem cells have the ability to become many types of body cells and can be used to repair or replace damaged cells in the body. While not as versatile as embryonic stem cells, cord blood stem cells have an advantage over bone marrow stem cells. When used in transplants, cord blood cells are less likely to trigger rejection in patients. Cord blood technology can be used to treat over seventy types of genetic illnesses.

Generally, the prospects of stem cell therapies are still far from clear. So far, they are not clinically applicable. In labs, growing the cells into heart cells, nerve cells, or whatever tissue is needed has proven extremely difficult. The actual survival of the cells is too poor. Many scientists believe effective stem cell therapies are still years away from human trials. The more immediate use for stem cells may be for researching and understanding disease. That knowledge could develop more conventional medicines and therapies.

Glossary

An *embryo* is an early stage of development of a multicellular organism. In general, in organisms that reproduce sexually, embryonic development refers to the portion of the life cycle that begins just after fertilization and continues through the formation of body structures, such as tissues and organs.

Abortion is the ending of a pregnancy by removal or expulsion of an embryo or fetus before it can survive outside the uterus. An abortion that occurs without intervention is known as a miscarriage or spontaneous abortion. When deliberate steps are taken to end a pregnancy, it is called an induced abortion, or less frequently "induced miscarriage". The unmodified word abortion generally refers to an induced abortion.

Assisted reproductive technology (ART) includes medical procedures used primarily to address infertility. This subject involves procedures such as in vitro fertilization, intracytoplasmic sperm injection (ICSI), cryopreservation of gametes or embryos, and/or the use of fertility medication.

In vitro fertilisation (IVF) is a process of fertilisation where an egg is combined with sperm outside the body, in vitro ("in glass"). The process involves monitoring and stimulating a woman's ovulatory process, removing an ovum or ova (egg or eggs) from the woman's ovaries and letting sperm fertilise them in a liquid in a laboratory. After the fertilised egg (zygote) undergoes embryo culture for 2–6 days, it is implanted in the same or another woman's uterus, with the intention of establishing a successful pregnancy.

Egg donation is the process by which a woman donates eggs to enable another woman to conceive as part of an assisted reproduction treatment or for biomedical research. For assisted reproduction purposes, egg donation typically involves in vitro fertilization technology, with the eggs being fertilized in the laboratory; more rarely, unfertilized eggs may be frozen and stored for later use. Egg donation is a third party reproduction as part of assisted reproductive technology.

Surrogacy is an arrangement, often supported by a legal agreement, whereby a woman (the surrogate mother) agrees to bear a child for another person or persons, who will become the child's parent(s) after birth.

Genetic engineering, also called *Genetic modification* or *Genetic manipulation*, is the direct manipulation of an organism's genes using biotechnology. It is a set of technologies used to change the genetic makeup of cells, including the transfer of genes within and across species boundaries to produce improved or novel organisms. New DNA is obtained by either isolating and copying the genetic material of interest using recombinant DNA methods or by artificially synthesising the DNA. A construct is usually created and used to insert this DNA into the host organism.

Somatic cell nuclear transfer (SCNT) - the technology in which the nucleus from a somatic cell (an ordinary body cell) of an organism is inserted into the de-nucleated egg of another (female) member of the same species (or even that of another species as with chimera), and triggered into developing as an embryo.

Cloning is the process of producing genetically identical individuals of an organism either naturally or artificially. In nature, many organisms produce clones through asexual reproduction. Cloning in biotechnology refers to the process of creating clones of organisms or copies of cells or DNA fragments (molecular cloning). Beyond biology, the term refers to the production of multiple copies of digital media or software.

Reproductive cloning: the use of SCNT to produce human embryos to implant into the wombs of women. This will produce human babies with genomes identical to the nucleus donors.

Therapeutic cloning: the use of SCNT to produce human embryos genetically identical to the nucleus donor. These embryos are then used for research, or for the harvesting of stem cells, then destroyed.

THEME 5. SOCIAL-PHILOSOPHICAL ASPECTS OF ETHICAL PROBLEMS IN MEDICINE

Plan

1. Social justice and socio-ethical obligations in medicine
2. Bioethical aspects of transplantology and blood transfusion
3. Bioethical problems of HIV-infection and other socially dangerous infections
4. Medical errors and iatrogeny

Key words: organ transplantation, autograft, xenograft, medical error, iatrogenesis.

Control Questions

1. What are the main ethical problems and approaches with respect to just distribution of medical resources?
2. What are the main ways of organizing national health care systems, and how they relate to the problem of social justice in medicine?
3. What are the main ethical problems of transplantation?
4. What are the criteria of the death of a person that allow taking organs for transplantation?
5. Give the definition of the term "medical error".
6. What is iatrogenesis? What are its main kinds and causes?

Task

Study the main international regulations on transplantation. Prepare a report (2-3 pages) on the main provisions of these regulations.

Recommended Reading

1. Zaporozhan V.M., Aryayev M.L. The Social Ethics of Medicine. Separate Ethical Problems of the Clinical Medicine // Zaporozhan V.M., Aryayev M.L. Bioethics. – Odessa: Odessa State Medical University, 2008. – P. 198-212, 222-230.

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4. Veatch R., Guidry-Grimes L. Social Ethics of Medicine: Allocating Resources, Health Insurance, Transplantation, and Human Subjects Research // Veatch R., Guidry-Grimes L. The basics of bioethics. – London, New York: Routledge, 2019. – P. 234-268.

Review of the Topic

Ethical problems of transplantology

Organ transplantation is a medical procedure in which an organ is removed from one body and placed in the body of a recipient, to replace a damaged or missing organ. The sources of organs for transplantation may be corpses, alive donors, artificial organs, animal organs (xenotransplants), fetal tissues.

The main ethical problems of transplantology are

- justifiability of the redistribution of medical resources for the development of transplantology;
- financial issues of making transplantation operations;
- problems of particular stages: constation of the death of a person on the brain death criteria; explantation of an organ or tissues from a corpse or a living person; distribution of the available organs of tissues.

Ethical and legislative regulation of after-death explantation of organs and tissues of humans involve three alternative approaches:

- procedural;
- based on the presumption of consent;
- based on the presumption of the lack of consent.

The distribution of organs for transplantation is based on the moral principles of utility and equality. To achieve justice in the distribution, a number of

considerations should be taken into account, such as donor-recipient compatibility, the time of waiting, the emergency, the distance between a recipient and an organ.

Ethical problems of AIDS (HIV). AIDS is an incurable disease caused by HIV-infection. HIV is a virus transmitted through liquids that enter human body, usually with sexual intercourse or blood. In 30-40% a baby of a HIV-infected mother is born HIV-infected.

The main ethical problems that arise with respect to HIV-infected patients are:

- informed consent to checkup and treatment;
- issues of social health;
- politicisation of the disease;
- the problem of the stigmatisation;
- confidentiality and the attitude of medical workers to a terminal disease.

The information about the positive result of the checkup on HIV leads to cardinal changes in the life of a person. A patient faces a difficult dilemma: either be honest and undergo the risk of rejection, or conceal the truth and endanger the life of the partner. The best way to prevent the promulgation of HIV is education and support for responsible sexual behaviour that involves care for the partner.

In blood transfusions, the physician that takes blood should ensure that the donor is not HIV-infected. The HIV-checkup is necessary.

Medical mistakes. Medical mistake is an action of a medical worker that results in unintended negative effects. Causes of medical mistakes can be divided into objective and subjective.

Objective causes include:

- inadequacy of the available relevant information: rapid "aging" of scientific knowledge, insufficient reliability of the available data, redundancy of information;
- lack of time for taking decision;

- unavailability of necessary methods of diagnostics and treatment;
- limited medical knowledge.

The main subjective causes are:

- specific features of the personality of the physician and his/her emotional state at the time of performing his/her work;
- the lack of experience and/or qualification that is not due to professional ignorance.

In order to prevent medical mistakes, a physician should follow deontological rules that involve the full competence as a form of professional integrity; constant careful checkup of the patient; rational caution; the capability to take decisions in difficult circumstances; full integrity with respect to professional duty.

Iatrogenesis. Iatrogenesis is health-damaging mental frustration of a patient due to the incorrect imprudent statements or actions of a medical worker. Iatrogenic disease is a disease that arise because of negative impact of the physician's behaviour or other medical factors on the mental state of a patient. Iatrogenic diseases develop in the conditions that involve emotional lability, distrust, and fear. The typical kind of a physician's behaviour responsible for iatrogenesis are mistaken diagnosis, inept explanation of the patient's condition or of particular manifestations of the decease, uncautious talk of a physician with other people about the patient's health. The prevention of iatrogenesis requires tactfulness and tolerance, understanding of the psychology of the patient, individual approach. Beneficent psychological climate and the healing role of conversation are of primary importance.

Glossary

Organ transplantation is a medical procedure in which an organ is removed from one body and placed in the body of a recipient, to replace a damaged or missing

organ. The donor and recipient may be at the same location, or organs may be transported from a donor site to another location.

An *autograft* is a transplant of tissue to the same person. Sometimes this is done with surplus tissue, tissue that can regenerate, or tissues more desperately needed elsewhere (examples include skin grafts, vein extraction for CABG, etc.).

A *xenograft* is a transplant of organs or tissue from one species to another. An example is porcine heart valve transplant, which is quite common and successful. Another example is attempted piscine-primate (fish to non-human primate) transplant of islet (i.e. pancreatic or insular tissue) tissue.

A *medical error* is a preventable adverse effect of care ("iatrogenesis"), whether or not it is evident or harmful to the patient. This might include an inaccurate or incomplete diagnosis or treatment of a disease, injury, syndrome, behavior, infection, or other ailment.

Iatrogenesis - an adverse effect on a person, resulting from activity of one or more other persons acting as healthcare professionals or promoting products or services as beneficial to health. Includes all adverse unforeseen outcomes as well as foreseen outcomes from medication or other medical treatment or intervention.

THEME 6. BIOETHICAL PROBLEMS OF LIFE, DYING, RESUSCITATION, AND DEATH. EUTHANASIA

Plan

1. The problems of life, dying, resuscitation, and death in philosophy and history of different cultures
2. The human rights to live and to die with dignity
3. Euthanasia: the concept, active and passive euthanasia. Iatrotanasia
4. Palliative care. Hospices.

Key words: euthanasia, passive euthanasia, active euthanasia, palliative care, hospice.

Control Questions

1. What are/were the views on euthanasia of different religions and philosophers?
2. Why is the problem of euthanasia became more acute in the 20-th century?
3. What is the difference between active and passive euthanasia?
4. How do different countries in the world treat euthanasia?
5. Which kind of euthanasia - active or passive - is more likely to be morally justifiable, and why?
6. Can iatrotanasia be morally justifiable?
7. What are the main principles of palliative care in hospices?

Task

Write an essay (2-3 pages) about your personal attitude towards euthanasia. Provide reasons for your attitude. Discuss the arguments of the opposite side.

Recommended reading

1. Bryant J., Velle L. Decisions at the End of Life: When May I Die and When Am I Dead // Bryant J., Velle L. Introduction to Bioethics. – Wiley-Blackwell, 2018. – P. 159-178.

2. Mooney C. The End of Life // Mooney K. Bioethics. – Lucent Books, 2009. – P. 38-52.
3. Talbot M. Aging and Death // Talbot M. Bioethics. An Introduction. – Cambridge University Press, 2012. – P. 203-246.
4. Veatch R., Guidry-Grimes L. The Principle of Avoiding Killing // Veatch R., Guidry-Grimes L. The basics of bioethics. – London, New York: Routledge, 2019. – P. 152-170.

Review of the Topic

The problems of life and death in philosophy and history of various cultures

The topic of death is one that greatly troubled people of all times and cultures. Human mortality is not merely a natural phenomenon but social phenomenon as well. Throughout its history, mankind tried to make sense of death and of life in the perspective of its mortality. The special awareness and importance of death is reflected in all religions and rites, especially the rites of burials, which was practiced in the eldest cultures, already with Neanderthals (more than about 40,000 years ago).

Spanish novelist and philosophers of 20-th century Miguel de Unamuno emphasized the role of the rite of burials for religion:

“It has been said a thousand times and in a thousand books that ancestor-worship is for the most part the source of primitive religions, and it may be strictly said that what most distinguishes man from the other animals is that, in one form or another, he guards his dead...; he is an animal that guards its dead. ... This cult, not of death but of immortality, originates and preserves religions.”¹¹

The fear of death has given rise, in many religions, to the idea of soul, as non-material entity distinct from the body, and its immortality. There are two major forms of this belief:

¹¹ Unamuno M. Tragic Sense of Life. – New York: Dover Publications, 1954.

1) the belief that the human soul, which was created by God, after the death of the body can continue its existence in another world (Aid, the Kingdom of Heaven, etc., - this belief is characteristic for monotheistic religions of Islam, Christianity and Judaism);

2) the belief that the human soul, after the death of the body can be reborn in another body (this belief is characteristic for religious traditions of India).

Philosophers, from ancient times, proposed their recipes of overcoming the fear of death.

So, the famous ancient Greek philosopher Socrates suggested that “no one knows whether death, which they in their fear apprehend to be the greatest evil, may not be the greatest good”. Moreover, “this fear of death is indeed the pretense of wisdom, and not real wisdom, being the appearance of knowing the unknown; ... conceit of knowledge, which is a disgraceful sort of ignorance”. He made a more detailed discussion of this issue:

“... there is great reason to hope that death is a good, for one of two things: – either death is a state of nothingness and utter unconsciousness, or, as men say, there is a change and migration of the soul from this world to another. Now if you suppose that there is no consciousness, but a sleep like the sleep of him who is undisturbed even by the sight of dreams, death will be an unspeakable gain. For if a person were to select the night in which his sleep was undisturbed even by dreams, and were to compare with this the other days and nights of his life, and then were to tell us how many days and nights he had passed in the course of his life better and more pleasantly than this one, I think that any man, I will not say a private man, but even the great king, will not find many such days or nights, when compared with the others. Now if death is like this, I say that to die is gain; for eternity is then only a single night. But if death is the journey to another place, and there, as men say, all the dead are, what good ... can be greater than this? If indeed when the pilgrim arrives in the world below, he is delivered from the professors of justice in this world, and finds the true

judges who are said to give judgment there, Minos and Rhadamanthus and Aeacus and Triptolemus, and other sons of God who were righteous in their own life, that pilgrimage will be worth making. What would not a man give if he might converse with Orpheus and Musaeus and Hesiod and Homer? ... I, too, shall have a wonderful interest in a place where I can converse with Palamedes, and Ajax the son of Telamon, and other heroes of old ... What would not a man give, O judges, to be able to examine the leader of the great Trojan expedition; or Odysseus or Sisyphus, or numberless others, men and women too! What infinite delight would there be in conversing with them and asking them questions!” (Plato. Apology)

Another famous ancient Greek philosopher who paid much attention to the problem of the emancipation from the fear of death was Epicurus. Epicurus was a materialist and did not believe in the afterlife. His recipe against the fear of death was as follows:

“Accustom yourself to believe that death is nothing to us, for good and evil imply awareness, and death is the privation of all awareness... Death, therefore, the most awful of evils, is nothing to us, seeing that, when we are, death is not come, and, when death is come, we are not. It is nothing, then, either to the living or to the dead, for with the living it is not and the dead exist no longer.” (Epicurus. Letter to Menoeceus)

The human rights to live and to die with dignity. The problem of the right for euthanasia. Active and passive euthanasia

Contemporary medicine makes a great contribution to the conditions that make the average lifetime longer and longer. With life prolongation, the focus shifts away from simply keeping people alive to helping them have a good quality of life.

With respect to people in very grave health conditions that cause great suffering this raises the problem of the right to a dignified death – to dispose of oneself, one’s life and death, freely, at one’s own discretion. One way to do it is the refusal of treatment in situations in which it is too painful, unpromising, and

leads to the loss of human dignity. The California Natural Death Act (1977) recognizes the rights of the terminally ill to refuse medical treatments and interventions.

More active ways of terminating one's own life are more debatable. Some religions, Christianity included, deny the right for a suicide because, according to their doctrines, only God, who had given life to a person, is to take it away. The person himself should not commit suicide, whatever are his sufferings – suicide is considered as a grave sin.

On the other hand, supporters of the right for a suicide argue that, besides suffering, some health conditions make the life of a person inconsistent so miserable that it loses its dignity. It is the moral right of the human being to end his life on his/her will in a dignified way rather than continue one's wretched existence.

One of the ancient defenders of the dignified self-caused death (suicide) was a Roman philosopher Lucius Annaeus Seneca, who wrote in the book titled "The Moral Letters to Lucilius":

"To a life, one should not always cling. For mere living is not a good, but living well. Accordingly, the wise man will live as long as he ought, not as long as he can. He always reflects concerning the quality, and not the quantity, of his life. ... Must I await the cruelty either of disease or of man, when I can depart through the midst of torture, and shake off my troubles? This is the one reason why we cannot complain of life: it keeps no one against his will. ... Every man ought to make his life acceptable to others besides himself, but his death to himself alone."

In the contemporary society, with weakening of the influence of religion, the right for a suicide finds wider support. Anyway, a person who makes this final step successfully cannot be punished any more in this world. The more burning issue connected with the right for a suicide is one that has to do with the involvement of another person in the causation of death of a person who wills to die. Usually, the person involved is a physician. The issue is about *the admissibility of euthanasia*.

Euthanasia (from Greek "easy death") – is helping a person to die, on his or her will, in order to end suffering (*active euthanasia*) or withdrawal of medical care that leads to death (*passive euthanasia*). Both kinds of euthanasia are associated with a number of ethical problems that raise hot debates. They become topics of movies such as “Million Dollar Baby” (2004), “The Sea Inside” (2004)

Ethical problems of resuscitation and passive euthanasia

The main ethical problems of resuscitation:

- The issue of saving the lives of incurable patients: are traditional medical ethical principles, which prescribe fighting for life “to the end”, right if the patient prefers "easy death“?
- In transplantation – the need to remove a “living” donor organ whose owner should be irretrievably dead.
- The prolongation of a patient’s life with the use of equipment: when switching off the equipment (that will result in the patient’s death) is morally justified?

The problem of the criterion of death. In traditional case, when the heart stopped beating and the lungs ceased breathing (the irreversible cessation of the cardiopulmonary system) the person was considered dead. However, situation has changed with new technologies that allow reanimation, heart and lung transplants, and long-term support of the partial functioning of the human body with technical means. In this situation, a more adequate criterion of death is ***brain death*** – the irreversible cessation of brain function. However, this criterion leaves an important problem due to the fact that brain function is not an absolute matter but a matter of degree. It is not the case that the brain always either functions or not; it can function but partially, and it is not clear which functions are necessary and sufficient for a person to be still alive. There are difficult cases in which brain continues to perform some functions, but a person is likely to have no conscious mental state and no chance of their recovery.

So, there is a clinical state called ***persistent vegetative state*** (PVS), when the brain is severely damaged, so that there is no thinking, no feeling, no

consciousness. (For such a state to be recognized as permanent, the patient should be in id during three months.) However, the patient is not entirely brain-dead. The brain still performs a number of functions, and there can be appearances that suggest that the patient is conscious: his/her eyes may be open and he/she may utter sounds without meaning; he/she may appear to smile, grimace, or cough. The difficult ethical problem is: whether the life (body-functioning) of such a patient should be supported by artificial means (which are expensive and could be used for saving other patients' lives) for an indefinitely long time?

On the other hand, there is the problem of mistaken diagnosis and the difficulty to distinguish cases of persistent vegetative state from the cases of *locked-in syndrome*, when a patient does have conscious mental states but is incapable to express them. Some researches using the latest technical achievements suggest that the percentage of such misdiagnosing is very high, nearly 40%. And there are other researches that testify that people with locked-in syndrome rate their quality of life unexpectedly high, so that stopping artificial support of their lives cannot be considered a suffering-ending act of mercy.

In most countries, *passive euthanasia* – the withdrawal of medical care that leads to the death of the patient – is allowed if there is an explicit and well-testified will of the patient for this purpose. The debatable issues arise when the patient is not in the state to make conscious sane decisions: the patient is unconscious and, by all reasonable medical criteria, is not expected to ever come to consciousness, or gravely demented (Alzheimer's disease, etc.). In such cases, should artificial life-support be continued for an indefinitely long time? If not, when (in what conditions) it should be stopped? Who is to decide? Is it the physician, or family members?

To alleviate this problem, The Patient Self-Determination Act was adopted in USA in 1990. According to the act, all hospitals must counsel patients about living wills and health care planning. Patients are proposed to make an *advance directive* – a legal document in which a person sets out his wishes on how his appointed 'attorneys' (representatives) should organize his life, health,

property and affairs, should he become mentally incompetent. However, there are some problems with applying advance directives: directives can be vague; it is impossible for people to fine-tune their directives in the way of medical care in advance; the future situations are complex, constantly changing, and often unpredictable. According to 2004 study, two-thirds of doctors said they would ignore advance directives in cases where a patient's prognosis remained hopeful or family members disagreed.

The problem of ethical permissibility of active euthanasia. Jatrotanasia

Active euthanasia is helping a person to die, on his or her will, in order to end suffering. In cases when a physician prepares means for a patient's death but the decisive action (final step) is taken by the patient himself, active euthanasia is called *assisted suicide*.

Basically, active euthanasia is ethically problematic because it involves the moral dilemma: on the one hand, there is the duty of a physician to save human life; on the other hand, there is the duty of a physician to alleviate suffering and the right of a patient to dispose of one's life.

Active euthanasia is most usually opposed on religious grounds: only God should decide when a person's life is taken away. Medical tradition is also not favorable to active euthanasia. Recollect the Hippocratic Oath:

I swear by ... by all the gods and goddesses, making them my witnesses ...

Neither will I administer a poison to anybody when asked to do so, nor will

I suggest such a course.

Opponents of active euthanasia raise a number of worries: Who defines terminally ill? How will doctors ensure patients have exhausted all other pain management options and are of sound mind to make this decision? Can the legalization of euthanasia lead to pressure on the elderly, uninsured, and disabled to choose suicide as the most cost-effective alternative? (However, with respect to the last worry, there is the reply that there is no evidence for this in states where euthanasia is legalized.) They are also afraid that legalizing euthanasia is a step

down a slippery slope that ends with the abandonment of the idea of the value of human life.

Among contemporary physicians, attitudes toward active euthanasia are divided. A number of medical organizations still follow the Hippocratic attitude. For example, the American Medical Association states:

“The power to assist in intentionally taking the life of a patient is antithetical to the central mission of healing that guides both medicine and nursing. It is a power that most health care professionals do not want and could not control.”¹²

On the other hand, public opinion and legislation on this issue gradually become more liberal. In USA doctor-assisted suicide became legally allowed first in the state Oregon, in 1997. Today, active euthanasia at the request of an incurable patient or doctor-assisted suicide is legalized in 8 US states, Netherlands, Belgium, Colombia. According to Gallup poll in USA in 2004, 65 percent of people said a doctor should be allowed to assist a suicide when a person was in pain and dying from an incurable disease.

Supporters of the legalization of euthanasia believe that the choice of death is an intrinsic human right. They argue that no harm is caused to any side, and that the danger of misuse can be prevented by careful regulation. Besides, an important consideration as the scarcity of medical resources, which can be used to save other lives.

In countries where active euthanasia is legalized, a number of safeguards is taken to prevent abuse. For example, Oregon’s Death with Dignity Act requires two separate requests, a written request with nonfamily witnesses, a second doctor’s review of the diagnosis and approval that the patient’s judgment is not impaired.

In other countries, active euthanasia remain legally forbidden and punishable. So, in Great Britain, the penalty for assisting a suicide is 14 years’

¹² Quot. in Mooney K. Bioethics. – p. 49.

imprisonment. However, the system of courts is such that in many cases this law is not applied. The legal persecution loses much of its efficiency because of “suicide tourism”: patients who want to undergo euthanasia can travel to other countries, in which it is legalized. Euthanasia for such a “tourists” is practiced on a large scale by *Dignitas* – an organization that helps people to die if they are able and willing to travel to Switzerland, where assisting suicide is legal. On August 2015, approximately 300 British citizens have travelled to Switzerland from the UK to die at one of Dignitas’ rented apartments in Zürich.

A further debatable issue is concerned with “double effect” of medical prescriptions. Unlike in case of euthanasia, it is widely agreed that to keep a patient comfortable, a doctor can prescribe as much of the drug as needed, even if it will shorten the patient’s life. However, the question arises: whether this is different, in principle, from euthanasia? Is not this sort of gradual euthanasia?

The ethically controversial character of the right for euthanasia can be well illustrated by the case of Jack Kevorkian – the physician who was called “Doctor Death”, because in 1990-th, he helped more than 120 people achieve their deaths (assisted suicide). He was also active campaigner for the right to die. In 1998, he performed active euthanasia in the state where it was forbidden and criminal, videotaped and aired it, - and, as a consequence, was convicted and imprisoned.

The activity of Kevorkian raised many strong criticisms not only on the ground of general opposition to euthanasia, but because of his methods. It seems that he was too enthusiastic about the right to die and carried away by campaigning for it. “According to a report by the *Detroit Free Press*, 60% of the patients who died with Kevorkian's help were not terminally ill, and at least 13 had not complained of pain; Kevorkian's counseling was too brief and lacked a psychiatric exam in at least 19 cases, 5 of which involved people with histories of depression; Kevorkian failed to refer at least 17 patients to a pain specialist after they complained of chronic pain, and sometimes failed to obtain a complete medical record for his patients...”

5. Iatrotanasia

Iatrotanasia (from Greek "iatros" – doctor, and "tanatos" – death): a doctor purposefully causes the death of a patient without his/her explicit will.

During World War II, Nazi Germany carried out a plan of iatrotanasia against the mentally handicapped, crippled, and physically deformed. The Nazis intended to purify their gene line and eliminate those they considered to be unworthy of life.

These programs eventually evolved into the genocide of Jews.

Unlike euthanasia, iatrotanasia cannot be plausibly justified, even by considerations of compassion to the patient undergoing strong suffering. The will of the patient should be decisive: the physician's compassion to suffering and his judgment that the patient's life is of so low quality that it is not worth continuation cannot outweigh the physician's duty to save life supported by the patient's will to continue living.

6. Palliative care. Hospices

Palliative care – a complex approach that aims to ensure the maximum quality of life for a patient with a terminal illness and his or her family by preventing and alleviating suffering through the early identification and accurate diagnosis (assessment) of emerging problems and adequate treatment (in cases of pain syndrome and other disorders of life), as well as providing psychosocial and moral support.

According to current international requirements, palliative medicine should be a necessary, integrated component of health care and social care. So, the Declaration of the World Health Organization (1990) and the Barcelona Declaration (1996) call upon all countries of the world to include palliative care in the structure of their national health systems.

High quality palliative care is a good alternative to euthanasia as a way of dealing with sufferings of terminally ill patients. So, in the US state of Oregon, where physician-assisted suicide is legal, 45% of patients who considered

euthanasia desirable but tried and were given good palliative care changed their view.

Hospice – a healthcare institution that provides palliative care to patients, usually in the terminal stages of disease, and their families. Its specialists have received special training in order to give organizational, methodological and consultative assistance and coordination of primary, general and specialized palliative care. The tasks of hospices are defined by the “Regulations on the specialized health care institution of special kind "Hospice"”.

American Cancer Society, on its Web site, describes the philosophy of hospice as follows:

“Hospice is a philosophy of care. ... The goal of hospice is to enable patients to continue an alert, pain-free life and to manage other symptoms so that their last days may be spent with dignity and quality, surrounded by their loved ones. ... it focuses on quality rather than length of life. It provides family-centered care and involves the patient and the family in making decisions.”¹³

For most people, the greatest fears about dying are losing control, feeling pain, and being alone. End-of-life care helps patients overcome these fears and experience a better quality of life in their final days.

Glossary

Euthanasia (from Greek: εὐθανασία; "good death": εὖ, eu; "well" or "good" + θάνατος, thanatos; "death") is the practice of intentionally ending a life to relieve pain and suffering.

Passive euthanasia entails the withholding treatment necessary for the continuance of life.

¹³ Cheyfitz K. Suicide Machine, Part 1: Kevorkian rushes to fulfill his clients' desire to die // Detroit Free Press, March 3, 1997.

Active euthanasia entails the use of lethal substances or forces (such as administering a lethal injection), and is the more controversial.

Palliative care (derived from the Latin root *palliare*, or "to cloak") is an interdisciplinary medical care-giving approach aimed at optimizing quality of life and mitigating suffering among people with serious, complex illness. Within the published literature, many definitions of palliative care exist; most notably, the World Health Organization describes palliative care as "an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial, and spiritual."

Hospice care is a type of health care that focuses on the palliation of a terminally ill patient's pain and symptoms and attending to their emotional and spiritual needs at the end of life. Hospice care prioritizes comfort and quality of life by reducing pain and suffering. Hospice care provides an alternative to therapies focused on life-prolonging measures that may be arduous, likely to cause more symptoms, or are not aligned with a person's goals.

THEME 7. FOUNDATIONS OF BIOSAFETY. THE HEALTHY WAY OF LIFE AS A CONDITION OF ITS DEVELOPMENT

Plan

1. The notion of biosafety. Legislative foundations of biosafety
2. Biological safety of work in laboratories
3. Problems of biosafety of the use of genetically modified organisms (GMO)
4. Human health. Healthy lifestyle
5. Medical Psychology. Applied aspects of medical psychology in various fields of biomedical ethics and deontology

Key words: biosafety, biosecurity, bioterrorism, agroterrorism, biological agent, biological warfare, genetically modified organisms, lifestyle, healthy lifestyle, bad habit, hypodynamia, stress, medical psychology, psychosomatics.

Control questions

1. What is the content of the concepts of biosafety and biosecurity?
2. What levels of the biological risks in laboratories are distinguished?
3. List the main potential threats to the biological nature of living organisms.
4. What is anthropogenic degradation of the environment?
5. What are main bioethical problems of genetic biotechnologies.
6. List and describe the risk assessment methods for biomedical technologies.
7. What is the content of the controversy about the development and use of GMO? What reasons are adduced by the opponents and defenders of GMO?
8. How GMO are used in medicine?
9. Explain the notion of health and its levels.
10. What is healthy lifestyle? What are its main constituents?
11. What are main models of promoting healthy lifestyle? What are their relative advantages and disadvantages?
12. What is the role of medical psychology in health promotion?

Task

1. Prepare a report (2-3 pages) about scientific assessment of the advantages and risks involved in the development and use of GMO.
2. Look for an information about an aspect of healthy lifestyle that is not widely known. Prepare a speech (2-3 pages) with a presentation (6-9 slides).

Recommended reading:

1. Biosafety and the environment [Электронный документ]. – Доступ: <https://www.cbd.int/doc/press/presskits/bs/cpbs-unep-cbd-en.pdf>
2. Bryant J., Velle L. Genetic Modification and Synthetic Biology. Genetic Modification of Plants // Bryant J., Velle L. Introduction to Bioethics. – Wiley-Blackwell, 2018. – P. 181-228.
3. Nicolia A., Manzo A., Veronesi F., Rosellini D. An overview of the last 10 years of genetically engineered crop safety research // Critical Reviews in Biotechnology. Published online 13 September 2013[Электронный документ]. – Доступ: <https://www.pps.net/cms/lib/OR01913224/Centricity/Domain/3337/peer%20reviewed%20meta%20study%20on%20GMOs%20copy.pdf>
4. Healthy lifestyle: 5 keys to a longer life (Harvard Medical School) [Электронный документ]. – Доступ: <https://www.health.harvard.edu/blog/healthy-lifestyle-5-keys-to-a-longer-life-2018070514186>

Review of the Topic:

The notion of biosafety. Biological safety of work in laboratories

Biosafety is the prevention, reduction, and elimination of the influence of dangerous biological factors (agents) on people, animals, plants, and environment.

Biosafety of the work in laboratories is concerned with the prevention or minimization of risks that depend mostly on the following factors:

- specific features of the organisms on which experiments are to be held;

- specific useful features of the experimental animals;
- the used technologies and procedures;
- the isolating devices and means.

Depending on to the level of biological danger, biological objects are classified into four groups.

Group I - the absence or low individual and social danger. Microorganisms that are not potential pathogens.

Group II - moderate individual danger, low social danger. Pathogenic microorganism that can cause decease but does not present serious danger for personnel, population, farm animals and environment. Carelessness in laboratory can evoke infection; however, it can be dealt with available treatment and prophylactic means. The danger of spread is limited.

Group III - high individual and low social risk. Pathogenic agent that usually evokes a serious decease but usually does not spread. Efficient treatment and prophylactic procedures are available.

Group IV - high individual and social risk. Pathogenic agent that usually evokes a serious decease and easily spreads. Means of efficient resistance are not available.

Legislative foundations of biosafety. A number of legislative acts regulates the issues of biosafety indirectly, by the formulation of the general requirements for healthcare, protection of environment from the influence of dangerous factors of physical, chemical, and biological nature. Some of the most important such acts are «The Foundations of the Laws of Ukraine on Healthcare», the Law of Ukraine «On Medicals», the Law of Ukraine «On the quality and safety of food products», the Law of Ukraine «On Pesticides and Agrochemicals», the Law of Ukraine «On Ecological Expertise».

The problems of biosafety of the use of genetically modified organisms

Genetically modified organisms (GMOs) are organisms in which genetic material (DNA) is modified in a way impossible in nature. At present, about 140 species of

different plants have been transformed. In recent years, genetically modified lines of soy, corn, rapeseed, cotton, alfalfa, papaya and pumpkin have appeared on the commercial markets. The world leaders in growing GM plants are United States, Argentina, Brazil, Canada, and China. Among EU countries, the highest number of reported GMO use belongs to France (28% of total EU countries), Italy (15%), Spain (14%), and the United Kingdom (12%).

Objections over the development of GMO's:

- Whether food produced from GMOs is safe?
- What impact growing them will have on the environment?
- Whether they may provoke an allergic reaction?
- Whether the transgenes could transfer to human cells?
- Accusations that scientists are "playing God"

Defenses of GMOs:

- There is a scientific consensus that currently available food derived from GM crops poses no greater risk to human health than conventional food.
- With more than 1,700 studies demonstrating their safety, GMOs are among the most studied subject in science.
- More than 275 organizations and scientific institutions support the safety of GM crops. These include the World Health Organization, the United Nations Development Programme, the Organization for Economic Co-operation and Development.
- In 2016, a group of 107 Nobel laureates signed a letter endorsing GMOs.
- GMO's are widely used in medicine. One of the most important earliest medical successes of GM-technologies was the production of human insulin.

One striking example of the possible great use of GMO is the new culture of rice – *Golden rice*. It is a sort of rice produced through genetic engineering to biosynthesize beta-carotene, a precursor of vitamin A, in the edible parts of rice. Usual rice does not contain it. Golden rice allows solving a grave medical problem – to prevent Vitamin-A deficiency. Vitamin A deficiency is estimated each year to kill 670,000 children under the age of 5 and cause an additional 500,000 cases of

irreversible childhood blindness. The replacement of usual rice with Golden rice would allow solving the greatest part of this problem, because for over half of the world's population, rice is a staple food crop; it provides 30–72% of the energy intake for people in Asian countries.

Human health and healthy lifestyle

In order to be healthy, our own constant and significant efforts are required. Nothing can replace them.

M. Amosov

Health is the set of physical, spiritual and social qualities of a person that is the foundation of his/her longevity and a necessary condition for the realization of creative plans, high working capacity, creation of a strong family, birth and raising children. Researches show that human health depends 20% on heredity, 10% on the level of development of medicine, 20% on the state of the environment and 50% on the lifestyle.

Lifestyle is a set of sustainable forms of human activity that determine his/her life path. It is a set of his/her habits. **Healthy lifestyle** implies adherence to certain rules that ensure harmonious development, high performance, spiritual equilibrium and health of a person. Healthy lifestyle involves practical actions aimed at preventing diseases, strengthening all systems of the body and improving the general well-being of a person. **Healthy lifestyle principles** include

- rational nutrition;
- optimum motor mode;
- tempering the body;
- personal hygienic care;
- absence of bad habits;
- positive emotions;
- intellectual development;
- moral and spiritual development;
- formation and development of volitional qualities.

2. Medical Psychology. Applied aspects of medical psychology in various fields of biomedical ethics and deontology

Medical psychology is an applied field of psychology that studies the regularities of functioning of the mind in the conditions of emergence and course of diseases, as well as the restoration of health. The focus of medical psychology is the relationship of the patient with the environment of the hospital (the relationship between physician and patient; nurse and patient; physician, nurse and patient). The founder of medical psychology is R.G. Lotze (German psychologist and philosopher of the nineteenth century). Medical psychology includes clinical psychology; clinical neuropsychology; psychopharmacology; pathopsychology, etc.

Subject matter of medical psychology includes:

- the personality of the patient;
- the personality of the medician;
- the relationship between the patient and the medical professional in different conditions (such as home visit, an outpatient clinic);
- the psychology of relations of medical workers in the course of their professional activity, in everyday life, etc.

The tasks of medical psychology are:

- the study of the specifics of mental changes in the conditions of somatic and mental illness;
- the study of mentally pathogenic life conditions and kinds of activity;
- the study of personal features that prevent or contribute to the disease.

Medical Psychology is divided into

- *general medical psychology*, which studies the personality of the patient, physician, middle and junior health care professionals and their relationship and
- *special medical psychology*, which studies the same issues in each specific medical discipline: surgery, therapy, pediatrics, psychiatry, neuropathology and others.

The most important methods of psychological research are observation and experiment. *Observation* is a purposeful, conditioned task of deliberate perception of mental phenomena and elucidation of their meaning. *Experiment* is an interaction between a subject (or a group of subjects) and an experimental situation organized by the researcher in order to establish the patterns of this interaction. The auxiliary methods of psychological research are clinical interview, testing, studying the products of mental activity of patients.

The main applied aspects of medical psychology in various fields of biomedical ethics and deontology are:

- psychological characteristics of patients with various diseases and in obstetrics;
- psychological aspects of dependent and suicidal behavior;
- psychological aspects of thanatology and euthanasia.

Glossary

Biosafety is the prevention of large-scale loss of biological integrity, focusing both on ecology and human health. These prevention mechanisms include conduction of regular reviews of the biosafety in laboratory settings, as well as strict guidelines to follow.

Biosecurity, as originally conceptualized, was a set of preventive measures designed to reduce the risk of transmission of infectious diseases in crops and livestock, quarantined pests, invasive alien species, and living modified organisms. From the 1990s, with in response to the threat of biological terrorism, biosecurity started including the prevention of the theft of biological materials from research laboratories. The emerging nature of second biosecurity threats means that small scale risks blow up rapidly, thus an effective policy becomes a challenge for there are limitations on time and resources available for analysing threats and estimating the likelihood of their occurrence.

Bioterrorism is terrorism involving the intentional release or dissemination of biological agents. These agents are bacteria, viruses, insects, fungi, or toxins,

and may be in a naturally occurring or a human-modified form, in much the same way in biological warfare. Further, modern agribusiness is vulnerable to anti-agricultural attacks by terrorists, and such attacks can seriously damage economy as well as consumer confidence. The later destructive activity is called agrobioterrorism and is subtype of agro-terrorism.

Agroterrorism, also known as **agriterrorism** and **agricultural terrorism**, is a malicious attempt to disrupt or destroy the agricultural industry and/or food supply system of a population through "the malicious use of plant or animal pathogens to cause devastating disease in the agricultural sectors". It is closely related to the concepts of biological warfare, chemical warfare and entomological warfare, except carried out by non-state parties.

Biological warfare (BW) – also known as germ warfare – is the use of biological toxins or infectious agents such as bacteria, viruses, insects, and fungi with the intent to kill or incapacitate humans, animals or plants as an act of war. Biological weapons (often termed "bio-weapons", "biological threat agents", or "bio-agents") are living organisms or replicating entities (viruses, which are not universally considered "alive"). Entomological (insect) warfare is a subtype of BW.

A **biological agent** (also called **bio-agent**, **biological threat agent**, **biological warfare agent**, **biological weapon**, or **bioweapon**) is a bacterium, virus, protozoan, parasite, or fungus that can be used purposefully as a weapon in bioterrorism or biological warfare (BW).[1] In addition to these living or replicating pathogens, toxins and biotoxins are also included among the bio-agents. More than 1,200 different kinds of potentially weaponizable bio-agents have been described and studied to date.

A **genetically modified organism (GMO)** is any organism whose genetic material has been altered using genetic engineering techniques. The exact definition of a genetically modified organism and what constitutes genetic engineering varies, with the most common being an organism altered in a way that "does not occur naturally by mating and/or natural recombination".

Lifestyle is the interests, opinions, behaviours, and behavioural orientations of an individual, group, or culture.

A **healthy lifestyle** is a way of living that lowers the risk of being seriously ill or dying early. Not all diseases are preventable, but a large proportion of deaths, particularly those from coronary heart disease and lung cancer, can be avoided.

A **bad habit** is a habitual behavior considered to be detrimental to one's physical or mental health and often linked to a lack of self-control. Habits that are typically seen as "bad" include smoking, nail-biting, procrastinating and swearing.

Hypodynamia – slow or diminished movement of body musculature.

In a medical or biological context **stress** is a physical, mental, or emotional factor that causes bodily or mental tension. Stresses can be external (from the environment, psychological, or social situations) or internal (illness, or from a medical procedure). Stress can initiate the "fight or flight" response, a complex reaction of neurologic and endocrinologic systems.

Medical psychology has historically been defined as the branch of psychology concerned with the application of psychological principles to the practice of medicine. Medical psychology shares with the fields of health psychology and behavioral medicine an interest in the ways in which biological, psychological, and social factors interact to influence health.

Psychosomatics – a branch of medical science dealing with interrelationships between the mind or emotions and the body and especially with the relation of psychic conflict to somatic symptomatology.

THEMES FOR REPORTS

1. Bioethical problems of the coexistence of "tradition" and "non-traditional" medicine.
2. Bioethical, legal, social problems of advertisement in medicine and pharmacy.
3. Moral, psychological, social aspects of desocialization and resocialization of patients.
4. Alcoholism, drug addiction, smoking: prevention, rehabilitation, re-socialization.
5. Palliative treatment as an alternative to euthanasia.
6. Bioethical problems of resuscitation.
7. Moral problems of suicide.
8. Euthanasia: the problem, judgments, searches for an alternative.
9. The vital meaning of choosing death.
10. The main problems of modern transplantology.
11. Transplantation and the identity of the human person.
12. Ethical/deontological dominants of dentistry, pharmacy, and surgery.
13. Bioethical and personal dimensions of medical practice.
14. Bioethics as a factor of the prevention of medical errors in medicine.
15. The principles of evidence-based medicine and their ethical significance.
16. Medical-ethical problems of human and animal cloning.
17. Bioethical criteria for biomedical manipulation and genetic engineering.
18. Biosafety issues in the context of bioethics.
19. Specific responsibilities of the geneticist for the family and the community.
20. Biomedical ethics of genetic research, medical genetic counselling, and population screening studies.
21. Man and illness. Illness as the experience and behavior of the human personality.
22. Medical-ethical and legal evaluation of error and iatrogeny in clinical practice.

23. National and international documents regulating the ethical, professional and legal activity of medical personnel.
24. Bioethical Aspects of medical paternalism in the doctor-patient relationship.
25. The content and meaning of the 1997 Council of Europe Convention "On the Protection of Human Rights and Dignity with Respect to the Use of Achievements in Biology and Medicine.
26. The content and meaning of the 1997 "Universal Declaration of the Genome of Human and Human Rights"
27. Euthanasia: pro and contra.
28. Ethical problems of reproductive medicine.
29. The problem of the right for abortion and other
30. Child rights and medicine.

TEST TASKS FOR THE FINAL CONTROL

1. Bioethics studies

- a) ethical problems that arise in medical practice and biomedical research
- b) ethical problems that arise in the process of biological evolution
- c) ethical views of biologists
- d) the development of ethics in biological systems

2. As translated from Greek, "bioethics" means

- a) ethics of life
- b) ethics of death
- c) meaning of life
- d) behaviour of living things

3. Academic bioethics studies

- a) moral standards of relationships in academic institutions
- b) general theoretical foundation for solving ethical problems in the biomedical field
- c) specific ethical issues encountered in medical practice
- d) relationship between biological systems

4. Clinical ethics studies

- a) relationship in medical teams
- b) ethical problems arising in medical practice
- c) moral standards of clinical research
- d) clinical manifestations of moral abnormalities

5. The foundations of the traditional medical ethics were formed in the school of

- a) Socrates
- b) Hippocrates

- c) Galen
- d) Paracelsus

6. In the teachings of Hippocrates, the understanding of the nature of disease and of the means of its treatment has character.

- a) religious
- b) magic
- c) naturalistic
- d) scientifically provable

7. The main principle of the medical ethics of Hippocrates:

- a) effective treatment
- b) love of humanity
- c) non-harming
- d) professionalism

8. The concept of deontology as a science of morality was introduced by

- a) Bentham
- b) Socrates
- c) Hippocrates
- d) Galen

9. The criterion of morality in the ethics of Bentham is

- a) humanity
- b) utility
- c) professionalism
- d) reciprocity

10. The concept of bioethics was introduced by

- a) Kant

- b) Bentham
- c) van Potter
- d) Aristotle

11. The Belmont report contains the formulation of three fundamental ethical principles of biomedical research. These are:

- a) respect for persons, beneficence, justice
- b) respect for persons, beneficence, humanism
- c) respect for persons, beneficence, utility calculation
- d) respect for persons, informed consent, justice

12. In biomedical research, the principle of respect for persons serves as a guide for

- a) informed consent
- b) risk/utility estimation
- c) fair selection of participants
- d) humanism

13. In biomedical research, the principle of beneficence serves as a guide for

- a) informed consent
- b) risk/utility estimation
- c) fair selection of participants
- d) humanism

14. In biomedical research, the principle of justice serves as a guide for

- a) informed consent
- b) risk/utility estimation
- c) fair selection of participants
- d) humanism

15. The main reason for the emergence of bioethics as the latest stage in the development of medical ethics is

- a) secularization of society
- b) deprofessionalization of medicine
- c) bureaucratization of medicine
- d) the development of biomedical knowledge and technology

16. By “the deprofessionalization of medicine” researchers understand

- a) the decrease in the effectiveness of medical care
- b) the loss by medicine of the character of a self-regulatory corporation
- c) incompetence of medical workers
- d) the replacement of medical workers with modern medical equipment

17. “Secularization of society” means

- a) the increased influence of religion
- b) the recognition of the sacredness of human life
- c) the weakening of the influence of religion
- d) the denial of the sacredness of human life

18. The term “moral pluralism” means that

- a) people differ in morality
- b) there are different ideas about morally permissible and impermissible among different nations
- c) people have different views on ethical issues and proceed from different moral systems
- d) there is no objective difference between good and evil

19. The main principle of the Nuremberg Code:

- a) Biomedical research should benefit society.

- b) A necessary requirement for biomedical experiments is the voluntary consent of the participants.
- c) Biomedical research should contribute to the development of science.
- d) In biomedical experiments on people suffering is impermissible.

20. The ethical principles of the Belmont Report were formulated for

- a) clinical practice
- b) regulation of the relationship between medical staff
- c) biomedical research on people
- d) biomedical animal research

21. The Hippocratic Oath DOES NOT contain the principle of

- a) non-harming
- b) sacredness of life
- c) social justice
- d) beneficence

22. The principle of respect for the autonomy of a patient means that

- a) a physician should not act to the detriment of the patient
- b) a physician must act for the good of the patient
- c) the patient gives informed consent
- d) health benefits should be distributed fairly

23. The development of medical ethics in the second half of the twentieth century proceeded in the direction to

- a) paternalism
- b) autonomy of the patient
- c) autonomy of the physician
- d) feminism

24. The principle of respect for the autonomy of a patient does NOT imply

- a) the patient being informed about his disease and ways of its treatment
- b) the patient's knowledge about the physician's values
- c) the patient's right for free medical care
- d) the patient's right to refuse the proposed treatment

25. The principle of patient autonomy can NOT be restricted on considerations of

- a) immaturity
- b) doctor's knowledge of the correct method of treatment
- c) mental disorders
- d) danger to other people
- e) conflict with the autonomy of the doctor

26. A patient's informed consent does NOT imply obtaining complete information about

- a) goals of the planned intervention
- b) expected positive consequences for the patient
- c) possible discomfort and risks
- d) mechanisms of action of the drugs
- e) existing alternative treatments

27. The principle of confidentiality means that information about the patient communicated to a physician or obtained as a result of medical research

- a) cannot be used to harm the patient
- b) should be used for medical purposes
- c) cannot be communicated to a third party without the permission of the patient
- d) can only be communicated to close relatives of the patient

28. The paternalistic model of physician-patient relationship implies that

- a) a physician takes care of a patient, makes decisions, and the patient accepts this care and follows the physician's instructions
- b) a physician and a patient have equal rights and make joint decisions on treatment methods
- c) a physician and a patient act according to a contract that defines their rights and obligations
- d) a physician acts as a friend of a patient
- e) a physician acts as a technician that provides services to a client-patient

29. The collegial model of physician-patient relationship implies that

- a) a physician takes care of a patient, makes decisions, and the patient accepts this care and follows the physician's instructions
- b) a physician and a patient have equal rights and make joint decisions on treatment methods
- c) a physician and a patient act according to a contract that defines their rights and obligations
- d) a physician acts as a friend of a patient
- e) a physician acts as a technician that provides services to a client-patient

30. The engineering model of physician-patient relationship implies that

- a) a physician takes care of a patient, makes decisions, and the patient accepts this care and follows the physician's instructions
- b) a physician and a patient have equal rights and make joint decisions on treatment methods
- c) a physician and a patient act according to a contract that defines their rights and obligations
- d) a physician acts as a friend of a patient
- e) a physician acts as a technician that provides services to a client-patient

31. Ethics of a nurse are formulated in

- a) the Hippocratic Oath
- b) the Florence Nightingale Pledge
- c) the Oath of a physician of Ukraine
- d) the Belmont report

32. The Florence Nightingale Pledge does not contain the principle of

- a) confidentiality
- b) non-harming
- c) patient autonomy
- d) professionalism
- e) beneficence

33. The basis of the ethical issue of abortion is

- a) woman's right to control her body
- b) the moment when the human body becomes a person who has the right to life
- c) the existence of the human soul
- d) the importance of procreation

34. The pro life attitude on abortion gives priority to

- a) woman's right to choose her way of life
- b) the right of the human embryo (fetus) to life
- c) woman's right to dispose of her body
- d) creation of the conditions for the preservation and development of life of all living beings

35. The pro choice attitude on abortion gives priority to

- a) woman's right to choose her way of life
- b) the right of the human embryo (fetus) to life
- c) woman's right to dispose of her body

d) creation of the conditions for the preservation and development of life of all living beings

36. The attitude of the largest world religions (Christianity, Islam) toward abortion:

- a) inadmissibility of abortion;
- b) admissibility of abortion only at an early stage, before the first heartbeat
- c) admissibility of abortion up to the birth of the child

37. Assisted reproductive technologies are

- a) medical technologies that contribute to the normal development of an embryo and the birth of a child for a woman in poor health
- b) medical technologies aimed at the birth of a child, with some or all stages of conception and development of the embryo carried out outside the body of the future mother
- c) technologies of operating a patient aimed at the birth of a child (cesarean section)

38. Extracorporeal (in vitro) fertilization is

- a) assisted reproductive technology in which donor's sperm is used for artificial insemination
- b) assisted reproductive technology in which donor's eggs are used for artificial insemination
- c) assisted reproductive technology in which an egg is removed from the body of a woman and fertilized artificially
- d) assisted reproductive technology in which the fetus is carried by a woman who is not a genetic mother

39. Surrogacy is

- a) assisted reproductive technology in which donor's sperm is used for artificial insemination

- b) assisted reproductive technology in which donor's eggs are used for artificial insemination
- c) assisted reproductive technology in which an egg is removed from the body of a woman and fertilized artificially
- d) assisted reproductive technology in which the fetus is carried by a woman who is not a genetic mother

40. The ethical issue of getting the status of mother by an elderly woman arises in connection with the technology of

- a) in vitro fertilization
- b) egg donation
- c) surrogacy
- d) sperm donation

41. Ethical issues associated with assisted reproductive technologies (ART) do NOT include:

- a) the problem of the high cost of ART, their inaccessibility for the poor
- b) the problem of the right of embryos to life
- c) the problem of the permissibility of extramarital sexual intercourse
- d) the problem of determining who should make decisions
- e) the problem of the right of single and homosexual women to parenthood through ART
- f) the danger of slipping into eugenics

42. Preimplantation genetic diagnostics is used

- a) to determine the genetic predisposition of parents to serious illnesses
- b) to determine the genetic predisposition of the embryo for the development of severe diseases and to screen out the embryos with the positive result
- c) to determine the chemical structure of the genes of the embryo

d) to select embryos with genetics that indicates a high probability of the desired physical and intellectual qualities of the person who will be born

43. The main problem associated with the use of genetic therapy:

- a) the risk of discrimination due to the violation of confidentiality
- b) the probability of harmful side effects due to the use of viruses for the transmission of genetic information
- c) the danger of eugenic use

44. Artificial creation of an exact genetic copy of an organism, organ or tissue

- a) proliferation
- b) duplication
- c) animation
- d) cloning
- e) generation

45. Ethical issue that is NOT related to human cloning

- a) the death of many underdeveloped human organisms in the process of experimentation and development of the technology
- b) the issue of the admissibility for a person to "play God"
- c) the problem of the ethical status of creatures with "artificial intelligence"
- d) the risk of creating human beings with significant physiological and psychological defects

46. The attitude of authoritative international medical and legal organizations, as well as national legislation, to human cloning:

- a) human cloning is unacceptable
- b) human cloning is acceptable
- c) human cloning is acceptable under certain conditions
- d) different attitudes of different organizations and states

47. The possibilities of the therapeutic use of stem cells include:

- a) antibacterial effect, strengthening immunity
- b) use in genetic therapy
- c) the restoration of individual tissues of the body and, in the future, the production of organs for transplantation
- d) use in assisted reproductive technologies

48. The therapeutic benefits of embryonic stem cells are due to the property:

- a) the ability to produce cells of the same kind
- b) the ability to produce cells many cells of many kinds
- c) the technology does not involve the destruction of embryos
- d) cells of the patient are used

49. The advantage of using adult stem cells, as compared to the use of embryonic ones:

- a) the ability to produce cells of the same kind
- b) the ability to produce cells many cells of many kinds
- c) the technology does not involve the destruction of embryos

50. The disadvantage of using induced pluripotent stem cells, as compared to conventional adult stem cells, is

- a) the ability to produce cells of the same kind
- b) the technology does not involve the destruction of embryos
- c) cells of the patient are used
- d) the use of viruses with the risk of dangerous side effects

51. A philosopher who taught that death should not be feared, because we do not know what death is and whether it is bad or good for us:

- a) Socrates
- b) Epicurus

- c) Seneca
- d) Unamuno
- e) Schopenhauer

52. A philosopher who taught that death should not be feared, because we never meet with it:

- a) Plato
- b) Aristotle
- c) Epicurus
- d) Unamuno
- e) Schopenhauer

53. A philosopher who defended the right to suicide as a condition for a decent life:

- a) Plato
- b) Aristotle
- c) Seneca
- d) Unamuno
- e) Schopenhauer

54. What does the term “euthanasia” mean in Greek?

- a) stem cell therapy
- b) easy death
- c) the acceleration of death with medication
- d) the doctor’s actions aimed at the resuscitation of the patient

55. Medical considerations against the euthanasia include:

- a) chance for recovery
- b) the possibility that the patient can change his/her mind
- c) the violation of the main prescription for a physician - saving people

d) all the factors in this list

56. Active euthanasia differs from passive in:

- a) active intervention by a physician in the process of the termination of a patient's life on his/her request
- b) requiring no consent of the patient's guardians
- c) the priority of the physician's decision over the patient's decision
- d) active intervention of society in medical processes

57. What does the term "passive euthanasia" mean?

- a) a physician's activity aimed at the continuation of human life
- b) a physician's activity aimed at the termination of a patient's life
- c) a physician's refusal from activities aimed at the support and prolongation of the patient's life
- d) intentional termination of the patient's life on his/her request

58. Permanent vegetative state is

- a) the constant non-consumption of the food of animal origin
- b) brain damage, in which the patient cannot express his/her states of consciousness
- c) brain damage, in which the patient has no consciousness (sensations, thinking, awareness) for more than 3 months
- d) brain damage in which the patient cannot move

59. The inadmissibility of euthanasia from the viewpoint of Christian ethics is connected with

- a) violation of the commandment "do not kill"
- b) the need for suffering
- c) opportunity to participate in the resurrection experience
- d) all the factors in this list

60. Kinds of euthanasia do not include:

- a) active
- b) physical
- c) passive

61. Who was called "the Doctor Death"?

- a) Jack Avonesyan
- b) Jack Kevorkyan
- c) Jack Tivoryan
- d) Jack Black

62. Active euthanasia is legalized in the following group of countries:

- a) Netherlands, Belgium, France
- b) Netherlands, Belgium, Switzerland
- c) Ukraine, Moldova, Belarus, USA
- d) Russia, Moldova, USA

63. The patient's right to refuse treatment is based on:

- a) the awareness of the insufficiency of funding
- b) the awareness of the limitations of medical facilities
- c) the acceptance of God's will
- d) the patient's will

64. Iatrotanasia is

- a) causing the death of a patient by a doctor in order to rid the patient of suffering on his/her request
- b) failure to provide medical care that leads to the death of the patient
- c) causing the death of the patient by the doctor without the explicit will of the patient
- d) the patient causing his own death in a state of affect

65. Palliative care is

- a) a complex medical measures for the treatment of especially severe cases
- b) complex care aimed at ensuring the best quality of life for a patient with a terminal disease
- c) financial assistance for poor patients for the purchase of medicines
- d) psychological assistance to patients with mental disorders, complementary to medication psychiatric treatment

66. Hospice is

- a) specialized medical institution for the treatment of seriously ill patients
- b) institution for palliative care
- c) specialized medical institution for the treatment of patients posing a threat to others
- d) institution for euthanasia

67. Which of the factors should not affect the doctor's decision with regard to difficult ethical problems in his/her professional sphere:

- a) deontological
- b) legislative
- c) traditional moral
- d) personal gain

68. The use of resuscitation equipment for a patient who is in critical condition is

- a) an application of the principle of struggle for human life to the end
- b) an abuse of therapeutic means
- c) a sign of the low qualification of a specialist
- d) an advantage of the availability of an appropriate insurance policy

69. An actor with a significant percentage of skin lesions gets into the burn compartment. He is conscious and asks the doctor to help him die, because he will no longer be able to engage in his profession. Doctor's actions should be:

- a) give the patient a sedative and invite a psychotherapist
- b) conduct resuscitation
- c) fulfill the request of the patient
- d) consult with the head doctor

70. What is active euthanasia?

- a) a physician's refusal from measures aimed at the prolongation of the patient's life
- b) a physician's actions aimed at the prolongation of the patient's life
- c) deliberate termination of the patient's life at the request of his/her relatives
- d) deliberate termination of the patient's life at his/her personal request

71. Bioterrorism is the use, as a means of the extermination and intimidation of people, of

- a) chemical agents
- b) biological agents
- c) physico-chemical agents
- d) all kinds of agents in this list

72. International and national systems of the management of biological risk include:

- a) informing population
- b) the system of control of bio-agents
- c) normative documents
- d) all the items in this list

73. How many levels of biosafety there are?

- a) one
- b) two
- c) three
- d) four

74. Biological danger is:

- a) the use of alternative treatments
- b) bacterial contamination of products
- c) non-compliance with the rules of personal hygiene
- d) inflicting harm to the health of a large number of people by means of biological agents

75. What belongs to GMOs?

- a) dietary supplements
- b) biological weapons
- c) genetically modified microorganisms
- d) all the items in this list

76. GMO can be defined as:

- a) an organism whose genotype was artificially modified in a way that is impossible in natural conditions
- b) a plant with artificially modified genotype
- c) an animal with artificially modified genotype

77. Which of the following factors does NOT serve as an ethical motivation for donation?

- a) love for people
- b) financial gain
- c) happiness of loved ones

78. What criterion is not taken into account in the selection of a donor?

- a) financial condition of the recipient
- b) compatibility
- c) the severity of the condition of the recipient
- d) time of being in the "waiting list"

79. When selecting patients for transplantation, the following criteria should be considered:

- a) therapeutic
- b) legal
- c) utilitarian
- d) all criteria in this list

80. In animal research, the replacement principle requires:

- a) not to use animals if there is a threat to their life
- b) if possible, to use other means or animals with a lower organization
- c) to reduce the number of animals on which the experiment is held
- d) to minimize suffering and improve the conditions of animals under experiment

81. In animal research, the principle of reduction requires:

- a) not to use animals if there is a threat to their life
- b) if possible, to use other means or animals with a lower organization
- c) to reduce the number of animals on which the experiment is held
- d) to minimize suffering and improve the conditions of animals under experiment

82. In animal research, the refinement principle requires:

- a) not to use animals if there is a threat to their life
- b) if possible, to use other means or animals with a lower organization
- c) to reduce the number of animals on which the experiment is held
- d) to minimize suffering and improve the conditions of animals under experiment

83. In biomedical experiments, the division into the experimental and control groups is necessary for

- a) objective assessment of the medical effectiveness of the drug by statistical comparison of the results of those who take it and those who do not
- b) objective assessment of the medical effectiveness of the drug by eliminating the placebo effect
- c) objective assessment of the medical efficacy of the drug due to the random selection of the organisms to which it is applied
- d) confidentiality

84. In biomedical experiments, randomization means that

- a) the selection in the experimental and control groups is carried out randomly
- b) the participants in the control group take an inactive substance, while believing that they are taking the medicine
- c) the patients and the medical staff who work with them do not know if the patient is taking the test drug or placebo

85. Placebo control means that

- a) the selection in the experimental and control groups is carried out randomly
- b) the participants in the control group take an inactive substance, while believing that they are taking the medicine
- c) the patients and the medical staff who work with them do not know if the patient is taking the test drug or placebo

86. A medical experiment is doubly blind if

- a) the selection in the experimental and control groups is carried out randomly
- b) the participants in the control group take an inactive substance, while believing that they are taking the medicine
- c) the patients and the medical staff who work with them do not know if the patient is taking the test drug or placebo

87. In biomedical experiments, randomization is needed in order to

- a) prevent the influence of human subjectivity in the process of selection into the experimental and control groups
- b) distinguish distinction between the medical effect of the test drug and the placebo effect
- c) ensure that participants in the control group cannot find out that they were taking a placebo rather than a medicine

88. In clinical trials, placebo control is needed to

- a) prevent the influence of human subjectivity in the process of selection into the experimental and control groups
- b) distinguish between the medical effect of the test drug and the effect of the change of the patient's mood due to the expectation of positive treatment results
- c) ensure that participants in the control group cannot find out that they were taking a placebo rather than a medicine

89. In clinical trials, “double blindness” is needed in order to

- a) prevent the influence of human subjectivity in the process of selection into the experimental and control groups
- b) distinguish distinction between the medical effect of the test drug and the placebo effect
- c) ensure that participants in the control group cannot find out that they were taking a placebo rather than a medicine

Recommended Sources

Basic

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Internet Information Resources

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2. Bioethics. Columbia University. – <http://www.bioethics.net>
3. Bioethics, from Wikipedia. – <https://en.wikipedia.org/wiki/Bioethics>
4. Canadian Bioethics Society. – <http://www.bioethics.ca>
5. Global Ethics Network. – <http://www.globalethicsnetwork.org/>
6. World medical association (declarations, conventions). – <https://www.wma.net/>

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