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MORAL AND ETHICAL PROBLEMS OF CONDUCTING CLINICAL TRIALS AND EXPERIMENTS ON HUMANS. ADOPTION OF THE PRINCIPLE OF INFORMED CONSENT.

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Abstract: *This article describes The World Health Organization (WHO) and the World Medical Association (WMA), recognizing the coexistence of various ethical and medical positions and moral and ideological orientations, regulate this coexistence with the help of international medical and ethical codes and agreements. Fundamental to the issue of informed consent are the Lisbon Declaration on the Rights of the Patient (WMA, 1981[1]) and the Declaration on Policies for Ensuring Patient Rights in Europe (WHO, 1994[2]).*

Introduction. The assertion of the principle of informed consent in the system of relations between a doctor and a patient is largely consistent not only with democratic processes in modern culture, but also with objective trends in the development of medical knowledge. For example, within the boundaries of "predictive medicine" using intrauterine diagnosis, it is possible to determine a person's predisposition to certain diseases. How to obtain consent to treatment if the patient does not have traditional, for example, pain symptoms of the disease? How should confidentiality be ensured? What should be the notification procedure? It is obvious that these factors, which today determine medical knowledge, actualize the problem of "information" and "consent", turning informed consent into a form of relationship between a doctor and a patient that is most consistent with the changes taking place in medicine. Historically, the concept of "informed consent" It was formed in the course of the work of the 1st

[1] Lissabonskaya deklaratsiya prav patsienta, prin. v 1981 g., Lissabon, Portugaliya, dopoln. v 1995 g., Bali, Indoneziya [Lisbon Declaration of Patients' Rights, adop. in 1981, Lisbon, Portugal; updated in 1995, Bali, Indonesia]. Available at URL: http://www.e-stomatology.ru/ star/info/2010/lissabon declaration. (accessed Jan. 20, 2012). [in Russian]

[2] Deklaratsiya o politike v oblasti obespecheniya prav patsientov v Evrope, Amsterdam, 1994 [Declaration of Policy in Sphere of Patients' Rights Assurance in Europe, Amsterdam, 1994]. Available at URL: http://europadonna.by/index . php?option=com_content&view=article&id=89:2010-01-18-11-42-13&catid=38:2010-01-10-09-32-1 1&Itemid=41 (accessed Feb. 14, 2012). [in Russian]

US Military Tribunal in Germany, which, along with the Judgment in the case of "medics" in 1947, prepared a document called the "Nuremberg Code", which became the first international "Code of rules for conducting experiments on humans". In the first paragraph of this Code, for the first time, the concept of “voluntary consent” of a person involved in a medical experiment is used.

Materials and methods. In 1947, on August 20, Nuremberg Tribunal completed its work, the defendants of which were 23 leading German medical scientists. The prosecutors and judges involved in the trial were shocked by the systematic and cold-blooded cruelty with which medical scientists conducted medical experiments on people with tuberculosis or malignant neoplasms, the disabled, the elderly, people with physical disabilities and the mentally ill, conducted experiments on prisoners of war and deported from occupied countries, newborns with “improper development” were killed, contrary to Hippocratic oath. A special industry of killing was created in the form of gas chambers, crematoria, etc. The International Military Tribunal in Nuremberg qualified these actions as crimes against humanity. The Nuremberg trials of 1947 demonstrated for the first time how fragile and unreliable, moral and ethical barriers that separate good from evil. 23 doctors appeared at the trial (of which 20 were Doctors of Sciences), including Hitler’s surgeon von Brandt. In the death camps, prisoners of war were vaccinated with typhus, tetanus, people cooled to +3 degrees C, abused children and women, transplanting bones from one person to another. Hippocratic Oath was not an obstacle for German doctors to conduct cruel inhuman experiments on prisoners of war. The death sentence, the suicide of several convicts in prison - this is the finale of the tragedy. Scary facts of history. They must not be repeated. One of the most important regulations of the Nuremberg Code was the ban on the experiments on a person without his voluntary consent. The Nuremberg Code, the most important document in the history of the ethics of medical experiments on humans, was adopted during the Nuremberg trials of fascist doctors who conducted experiments on prisoners of war. Numerous testimonies of the subjects (it would be more accurate to say - victims), as well as the results of experiments collected

and summarized with pedantry, which were at the disposal of the court, lined up in a terrible picture. Never in the history of human experiments have they been carried out with such sadism as they did during the Nazi era. Here are just a few of the facts given in the opening speech by the Chief Prosecutor at the trial, US Attorney Telford Taylor. Experiments carried out with the approval of Himmler, which studied the reactions of the body to high altitudes and rarefied air. In the Dachau concentration camp, imprisoned Jews, Poles and Russians endured the effect of lack of oxygen in atmospheric conditions at altitude of 12 km. Usually the subject was dead within half an hour; at the same time, the successive stages of his suffering were carefully recorded in the protocol of the experiment (for example, "spasmodic convulsions", "agonistic convulsive breathing", "groans", "shrill cries", "convulsions of arms and legs", "grimaces, biting of one's own tongue", " inability to respond to speech") and electrocardiogram data were recorded. These experiments, which were intended to help German pilots, were subsequently supplemented by the study of hypothermia, when the subjects were kept naked in frost up to 29 degrees for 9-14 hours or placed in ice water for several hours.

Experiments were carried out in the same concentration camp, during which over 1200 healthy people (including Catholic priests) were infected with malaria. Thirty subjects died directly from malaria, from 300 to 400 from complications caused by it, many others from excessive doses of neosalvarin and pyridone.

Experiments with mustard gas were carried out at Sachsenhausen, Natzweiler and other camps. The test subjects were deliberately injured, and then the wounds were infected with mustard gas. Others were forced to inhale the gas or ingest it in liquefied form. "Experimenters" reported that when gas was injected into wounds on the hands, the hands swelled greatly, and the person experienced extreme pain. The experiments, conducted mainly on women at the Ravensbrück camp, explored wound infections, as well as the possibilities of bone, muscle and nerve regeneration and bone transplantation. So, incisions were made on the subjects' legs, and then bacterial cultures, pieces of wood shavings or glass were introduced into the wounds. Only a few days later, the wounds began to be treated,

testing certain methods. In other cases, the wounds became infected with gangrene, after which some subjects began to be treated, while others from the control groups were left without treatment. Regarding transplantation experiments, for example, in one case a scapular bone was removed from a prisoner in Ravensbrück for transplantation.

Dachau explored the possibility of using sea water for drinking. At the same time, one group of subjects was not given water at all, the other drank ordinary sea water, the third sea water containing salt, but devoid of salty taste, and the fourth demineralized sea water. The experiment was carried out for 4 weeks on 40 subjects. The question of who should be tested on Jews or Gypsies was specially discussed, since some doubted whether the data obtained in experiments on Gypsies would be applicable to Germans. In the end, Himmler nevertheless decided to conduct experiments on gypsies. In other experiments, infectious jaundice was studied on concentration camp prisoners; methods were developed for cheap, "insensitive" and rapid sterilization of people so that in the future the Germans could populate the territories occupied by Poles and Russians; mass infection of people with typhus was carried out; studied the speed and nature of the action of poisons, which in Buchenwald were mixed into the food of Russian prisoners of war; the effect on the body of phosphorus compounds contained in English incendiary bombs was tested.

To replenish the anthropological collection at the University of Strasbourg in the Auschwitz camp, 79 Jews, 30 Jewish women, 2 Poles and 4 Asians were selected. In total, the "researchers" selected 1,200 Jews. After photographing and anthropological measurements, they were all killed, and their corpses were transported to Strasbourg. The Nuremberg Tribunal was not limited to punishing criminals. The verdict included a section called "Permissible Medical Experiments", later it became known as the "Nuremberg Code" and acquired an independent meaning, becoming the first international document in history regulating the conduct of medical experiments on humans. Its preamble noted: "The weight of the evidence before us leads us to conclude that certain types of

medical experiments on humans are ethical for the medical profession as a whole only if their conduct is limited to appropriate, well-defined limits."

Although the "Code" was adopted in the form of a court decision, it had and still has not so much legal as ethical force. It includes ten principles, the first of which is: "The absolutely necessary condition is the voluntary consent of the subject." This means that the person involved in the experiment must have the legal capacity to give consent; the situation in which he finds himself must allow him to exercise free choice without the influence of any elements of violence, deceit, fraud, cunning or other hidden forms of pressure or coercion; have sufficient knowledge to understand the details of the experimental procedure and make an informed decision. In the Nuremberg Code, for the first time in the history of mankind, the idea of the primacy of the good and interests of the individual over the interests of both science and society was put forward. For all its apparent simplicity, this idea can be considered a fundamental achievement in the moral experience of mankind. The norm of voluntary consent contained in the first article of the Nuremberg Code became a specific mechanism for protecting the subjects. In subsequent years, many other documents were adopted that regulated the practice of biomedical experiments in more detail and strictly (in particular, at present, in legal and ethical regulations, it is customary to speak of informed consent rather than voluntary consent, which is a more stringent norm), but the Nuremberg code" and to this day retains the function of the fundamental model.

Subsequently, the concept of "informed consent" begins to be used in the practice of US legal proceedings and is associated with a certain order of court cases for compensation for harm caused by negligent treatment. In the 1950s and 1960s, the term informed consent itself and the corresponding practice of recognizing the obligation of a doctor to inform the patient about the risk of medical intervention, about alternative forms of treatment, appeared before he gives consent to medical treatment. And if in the 50s the information was of a professional nature, then in the 70s the “patient-oriented” criterion was introduced for information, according to which the information should be given in a publicly

accessible form and include three parameters: a description of the goal treatment, possible risk and existing alternatives to the proposed treatment. Currently, in US jurisprudence, informed consent is the legal criterion for whether and to what extent care was provided by a physician to a patient. The principle of informed consent can be considered as a long-sought and finally found form of legal protection of a patient that restores the original, natural and actual inequality in relation to the doctor-patient. The patient, who, as a rule, does not have special medical knowledge, is doomed in advance to depend on the doctor, relying on his professionalism. On the one hand, this inequality is the risk of a patient trusting his health, dignity, and life to a doctor. On the other hand, the risk of a doctor who is not insured against so-called “medical errors”, which, however, legally qualify as “non-punishable conscientious error in the absence of negligence” or as “a circumstance mitigating the responsibility of a doctor”.

A kind of compensation for this "natural inequality" is to provide the patient with full legal protection. Its main forms include: the right to consent to medical intervention and to refuse it, the patient's right to information about the state of health and the duty of the doctor and medical institution to ensure this right.

A few decades ago, the traditional ideal for Euro-American civilization of the relationship between doctor and patient was "paternalism". This "paternal" or "parental" model assumed a thorough study by the doctor of the patient's condition, the doctor's choice for each specific case of treatment aimed at eliminating pain and its causes. The patient's consent to the planned intervention was determined by the choice of treatment methods made by the doctor. One of the reasons for the retreat from paternalism in the second half of the 20th century is the practically revolutionary changes in medical science, which led to fundamentally new possibilities for influencing and managing human life. This retreat was especially easy in the US, where there was and still is no legal right to health care, i.e., the right to health care is not guaranteed by the state (except when a person is in acute, life-threatening conditions). If bioethics focuses on the life problems of any living

being, then biomedical ethics (BME) concretizes the principles of bioethics in relation to a person.

Conclusion. Biomedical ethics is an ethical and applied discipline, the subject of which is the moral attitude of society as a whole and professionals - doctors and biologists in particular - to a person, his life, health, death, and which sets itself the task of making their protection a priority right of every person. In contrast to the "traditional" medical ethics, BME is integrative in nature, uniting, linking, concentrating common bioethical problems and requirements; at the same time, it relies on the so-called medical incidents - specific situations, turning them into precedents that become the basis for ethical generalizations, conclusions and subsequent recommendations. This is the situational nature of BME. The range of the main problems of the BME: establishing the status and role of moral values in the professional activities of physicians and biologists; resolution of moral conflicts in specific situations that arise in the process of biomedical research and treatment of patients; ethical regulation of interpersonal relations in the system of vertical and horizontal connections in the field of medicine. BME solves its problems not on a professional-corporate basis, but on a broader basis, with the involvement of representatives of other professions and the general public. The development of new medical technologies leads to the fact that today the relationship between the doctor and the patient is undergoing significant changes. If earlier the patient simply entrusted the doctor with the solution of questions about his treatment and even life, now he increasingly demands information about what is offered to him in this regard. In the United States, the practice has become widespread when the patient even "follows" the doctor, meaning the possibility of a lawsuit for "wrong treatment". Therefore, the role of the doctor is increasingly being replaced by the role of a consultant, adviser or competent professional expert, shaping the patient's decision making and informing the patient about the state of his health, the benefits and risks of possible interventions. The rights of patients in medical interventions are protected not only by the rule of truthfulness and the rule of confidentiality, but also by the rule of voluntary informed consent.

According to this rule, any intervention, including when conducting experiments on humans, must include the voluntary consent of the patient. In turn, the doctor must inform the patient about the goals, methods, side effects, possible risks, duration and expected results of the study. For the first time, the rule of "free consent" is formulated in the Nuremberg Code (1947) - the first "Code of rules on conducting experiments on humans." Then the principle of “free consent” began to be considered in the United States in litigation for damages for negligent treatment. The term “informed consent” has taken root in Europe 10 years later. In practice, indeed, a situation of natural inequality develops between the doctor and the patient. The patient without special medical knowledge trusts the doctor with his life. But the doctor himself is not immune from medical errors. The legal protection of the patient eliminates this inequality, and the principle of voluntary informed consent establishes new norms for the relationship between the doctor and the patient. The concept of voluntary informed consent establishes the duty of the doctor to inform the patient, as well as respect the patient's privacy, be truthful and keep medical confidentiality on the one hand, but on the other hand, this principle obliges the doctor to accept the patient's subjective decision for execution. The incompetence of the patient can render this model of doctor-patient relationship sterile and even harmful to the patient himself, as well as cause alienation between patient and doctor. A positive feature of voluntary informed consent is that it is aimed at protecting the patient from the experimental and testing intentions of the doctor and researcher, at reducing the risk of causing moral or material damage. At the same time, in a situation where harm has occurred, although voluntary informed consent was issued between the doctor and the patient, it is a form of protection for the doctor, weakening the legal position of the patient.

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