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THE BIOETHICAL BASIS OF CLINICAL ENGINEERING

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This is an attempt to analyze the phenomenon of a clinical engineering and clinical engineer`s position in terms of the norms and principles of bioethics. There is proved the presence of feedback in the bioethical regulation of development, testing and maintenance of biomedical devices, and the importance in this regard, the institute of clinical engineering. It was found that the clinical engineer is a translator of a competences, capable to a comprehensive, summary analysis of the technical and clinical incidents in the operation of medical equipment with the construction of generalizing conclusions that are suitable for consideration from the standpoint of bioethics, and to the implementation of formalized and non-formalized regulations, standards and elements of a clinical experience in the development phase of new types of biomedical equipment and materials.

Key words: *clinical engineering, medical equipment, life cycle, bioethical control, feedback.*

БИОЭТИЧЕСКИЕ ОСНОВЫ КЛИНИЧЕСКОГО ИНЖИНИРИНГА

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В работе делается попытка анализа такого явления, как клинический инжиниринг, и положения клинического инженера с точки зрения норм и принципов биоэтики. Показано наличие обратной связи в области биоэтического регулирования разработки, испытаний и эксплуатации биомедицинских устройств, а также важность в этой связи института клинического инжиниринга. Установлено, что клинический инженер является транслятором компетенций, способным как к комплексному, обобщающему анализу технических и клинических эксцессов при эксплуатации медицинской техники с выдачей обобщающих заключений, пригодных для рассмотрения с позиций биоэтики, так и к имплементации, формализованных и неформализованных нормативных положений, стандартов и элементов клинического опыта на этапе разработки и проектирование новых видов биомедицинского оборудования и материалов.

Ключевые слова: *клинический инжиниринг, медицинская техника, жизненный цикл, биоэтический контроль, обратная связь.*

Clinical engineering was originated in the western countries in the second half of the XX century as a response to the rapid increase the practical public health`s dependency from the complex electronic devices. This area of activity is associated mainly with medical equipment, but also associated with the study of the interactions between the effects of drugs, medical procedures and medical equipment to the extent that is necessary to ensure maximum safety and effectiveness of the treatment process. Scope of clinical engineers is growing with increasing of use of sophisticated medical equipment and includes not only hospitals but also clinics and outpatient medical facilities, as well as the development and testing of medical equipment.

The prevailing opinion about the engineer in the health care system is as a member of the medical institution`s administration or as a specialist for repair and maintenance of medical equipment. Despite the importance of these areas of activity of clinical engineers, it must be marked that their main task is to ensure the safe operation of technical medical institution as a whole, the improvement of health care delivery technology and to maximize the use of available technical possibilities in the treatment process. In addition, having basic engineering skills, as well as the biomedical, a clinical engineer should be an important part of providing feedback of producers and consumers of sophisticated medical equipment,

because only clinical engineer is capable to make technically competent and based recommendations for improvement of using this class of equipment.

In general, the main objective of the clinical engineer in the health system structure is the introduction and deployment of technical systems designed to improve the efficiency of treatment and diagnostic work. These technical systems are applicable for measuring various physiological parameters, the studying of organs and systems, recovery, etc. Over time, these technical systems are becoming more complex, their application requires consideration of a growing number of factors, among them a prominent place occupied by ethical and deontological factors. Consideration of these factors is also required at the stage of development and testing of medical devices and equipment. The development of new medical equipment samples, engineering staff should first of all ensure the safety of devices developed for all participants in the diagnostic and treatment process. To do this, this staff must know not only the risks associated with a particular kind of medical equipment, but also the physical and cultural characteristics of patients and medical operators of such equipment. At the stage of testing of new medical equipment is usually not possible to fully assess the range of possible risks associated with this technique. Therefore, the development and use of medical equipment must be carried out in strict conformity with the principles and norms of bioethics.

We know many examples of how the development and use of medical equipment for economic reasons sacrificed the safety of participants in the diagnostic and treatment process. That is why in developed countries the process of development and introduction of new medical technologies and implementing these medical technologies are regulated more and more regulations and is linked to the control of the various national and international organizations. One type of such control is a monitoring of compliance with the principles of bioethics. Schematically the process of bioethical control at different stages of the life cycle of medical equipment is shown in Fig. 1.

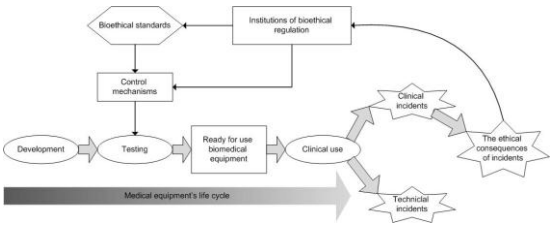

Fig. 1. The scheme of bioethical control at the different stages of medical equipment`s life cycle.

This scheme illustrates the presence of feedback, which allows making adjustments to the provisions of bioethical positions, which subsequently forms the basis of international and national standards. In accordance with those standards the development and testing of medical devices depends on the detected ethical implications of the practical application of this equipment. The presence of such feedback is especially important when rapid advances in medical technology leading to frequent occurrence not previously described the ethical implications of its use. The presence of such feedback can be illustrated by some historical examples. Importance of bioethical regulation of biomedical research and their technical support has become most evident against the background of accelerating technological progress and the associated large-scale incidents that took place in the first half of the twentieth century. Thus, after the WW II was adopted "Nuremberg Code", which consisted of 10 items, defines the basic ethical requirements for conducting experiments on humans. Similar experiments were valid only if they bear for the benefit of society and carried out in accordance with the moral, ethical and legal stipulations. [1]

The further development of common principles of bioethical regulation is inspired by clinical consequences of excesses that became a consequence of the imperfection of biomedical research structures, such as the incident, widely known as "thalidomide tragedy" [3]. The adoption of the Helsinki Declaration, based on the principles of the Nuremberg Code and improve its treatment was the response of the global medical community on this tragedy [4]. There is quite a lot of social institutions bioethical regulation on local, national and international levels. Compliance to bioethical standard, set by these organizations is more important for the successful and rapid implementation in practical public health of new types of medical equipment. At the international level, there are international and the Intergovernmental Bioethics

Committee. At the international level in the field of bioethics, regulation is based on the Universal Declaration on the Human Genome and Human Rights; Universal Declaration on Bioethics and Human Rights; to protect the rights and dignity of the Convention in relation to the application of biology and medicine and the Convention on Human Rights and Biomedicine [5].

Another quite noticeable, although local, act concerning the ethical review of biomedical research has become accepted in the United States in 1974 "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research". [6] This document includes three main principles or concepts that describe the desired structure of relations between the parties biomedical research conducted on human beings. The principles contained in this report, include the principle of respect for the individual, as the research object, its sovereignty and autonomy; the principle of profitability, which requires participants to medical and biological experiments to minimize the risks for themselves at maximizing the benefits of the experiment; the principle of justice, aimed at mitigating the socio-economic effects on the conduct of biomedical experiments that took place, for example, in the XIX century, when the poor patients for the possibility of treatment put risky experiments, the results of which are used without the risk for the wealthy patients.

The basic organizational structure performing ethical control over the process of testing and use in biomedical devices and materials in practice at present is so-called "Review Board". This structure is organized as a local independent ethics committee [5]. One of the main requirements to the members of such committees is a personal lack of interest in the results of the study, the lack of organizational, professional and economic dependence on people or organizations with an interest in a particular outcome research. Research of new materials and equipment is impossible without a positive opinion of the ethics committee. For this positive conclusion the researcher must prove the Committee that the planned research is not contrary to the bioethics principles and the fundamental documents of the above. In this case the researcher must submit a detailed experimental design, show its usefulness and safety. If the study is conducted in public, voluntary and awareness of their decision must be confirmed by the participation in the experiment by submitting to the committee informed consent to participate.The last point now should be favored as particularly important.

Currently, manipulations on human objects cannot be allowed while the formal informed consent was obtained. The obtaining of informed consent for tests of the new biomedical materials or equipment on humans usually includes following steps:

1.Provide participant complete and accurate information about the study;

2.Provision of party study the possibility to get answers to questions relating to his participation in the study;

3.Check the full perception and awareness of the party received information about the study;

4.Preparation of voluntary consent to participate in the study;

5.Information support participants throughout the study.

Briefly, the foregoing principles of bioethics control are now part of the conceptual framework, which is used in the construction of local and international standards in the field of medical equipment and supplies. Institutionally, it is the construction going on at the level of national standards agencies (e.g., in the Russian Federation it is the Federal Agency for Technical Regulation and Metrology) or global institutions of technical standardization. The latter include the International electro Commission (IEC), which is associated with the standardization of electrical medical devices; International Telecommunication Union (ITU), is responsible for standardization in the field of medical technology and data transmission technology; International Organization for Standardization (ISO), standardizing other types of medical and biological equipment and materials. Compliance with international standards, a constructed within these organizations, enables enterprises to developers of medical equipment to minimize the risk of errors at the stage of development and testing of new medical equipment, avoid duplication of documentation for such equipment and improve the image of the equipment and its products.The most common security classification system is the classification of medical equipment risks associated with excesses in the operation, the American mega-regulator used in this area - FDA. The Russian analogue in this area is the classification described in GOST R 51609-2000 [2]. Under this system, each medical device can be assigned to

one of three classes: Class 1 devices with the lowest risk in the case of clinical or technical incidents in the operation of up to 3 classes with the greatest danger of such excesses.

Summarizing, we can distinguish horizontal and vertical semi-horizontal standards in the field of biomedical equipment and materials. The first group includes standards governing the safety of the general principles applicable to a broad range of biomedical equipment and materials. This group includes, for example, ISO 10993 [9] standard, which describes the minimum requirements for checking the biocompatibility of any medical equipment. The group semi-horizontal standards include standards which specify the position of the first group of standards for specific groups of medical equipment and supplies. For example, ISO 7405 [10] standard regulates the preclinical assessment of biocompatibility of dental medical devices and materials. Vertical standards are an extension of the provisions of the first two groups of standards and concern the properties of specific types of medical equipment and supplies. For example, ISO 7197 [8] standard describes the requirements for biocompatibility of neurosurgical implants, as drainage shunts used in hydrocephalus. At present the main problems in the area of standardization of medical equipment and materials is the lack of international standards for newly developed innovative equipment, leading to an increased risk of incidents during its operation, as well as the contradictions between the various national standards that impede the use of equipment and materials in some countries.

The medical equipment compliance with relevant international and national standards it is important to evaluate its safety, which is a crucial area of activity of clinical engineering. Clinical engineer should know techniques of risk management, to participate in the study due to technical and clinical incidents during operation of medical equipment. Integrated assessments in this area require a systematic approach and try to account for the possible action of patients, medical equipment and environmental conditions of medical users of the environment. Another important area of activities of clinical engineering is the practical management of health technologies. This area of activity includes strategic planning equipping of health facilities, evaluation of the scope of use, direct and indirect costs of medical technologies used, evaluating the effectiveness of the use of medical equipment, development of schemes of service of various groups of medical equipment and planning to replace them. All these activities of clinical engineering should be based on norms and principles of bioethics.

The clinical engineer it is not only a personal agent in the management of health technologies, but is also an important link in the feedback chain of bioethics regulation of development and use of medical technology (Fig. 1). As such regulator, this engineer is the translator of competences for the analysis of the technical and clinical incidents in the operation of medical equipment with the issuance of generalizing conclusions that are suitable for consideration with bioethical positions, as well as to the implementation of formalized and non-formalized regulations, standards and elements of clinical experience in the development phase and the design of new types of biomedical equipment and materials. Such an understanding of the role and place of the clinical engineer in the health system structure allows us to formulate some concrete, practical principles that should be guided by clinical engineer in practice. At the same time clinical engineer should:

Monitor compliance with biomedical equipment and material provisions of the currently valid standards;

• Take all necessary measures to reduce the risk of damage associated with technical or clinical excesses during testing or operation of medical equipment;

• In case of any technical or clinical incidents during testing or operation of medical equipment, quickly analyze their causes and to inform about the results of this analysis are interested organizations;

• A clear understanding of their level of responsibility, their place in the structure of the medical institution, correlating it with their experience and knowledge.

• Discover and disclose any conflicts of interest that may have the relations to received and transmitted medical information.

• Ensure the protection of the confidentiality of medical information.

• Contribute to improving access to health care for all in need.

• Use all opportunities to reduce the cost of treatment due to more fully utilize the potential of modern technology in health care.

• Popularize the profession of clinical engineer, informed the representatives of the medical community about the role of the clinical engineer, a conductor in health technologies.

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APPLIED BIOETHICS

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BIOETHICAL ASPECTS OF MEDICAL DISCOURSE

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There has been insufficient research into the problems of institutional interaction of the participants of health care provision sphere which should be conceptualized from the biomedical paradigm perspective. The article aimed to reveal bioethical aspects of medical discourse. The authors substantiated their understanding of medical discourse and presented its genre typology. The genre of clinicopathological conferences was explored. This type of medical discourse was found to be the concentrated embodiment of the biomedical perspective of conceptualizing health reality. Alongside with the biomedical approach, bioethical principles of considering and presenting discoursive medical knowledge were employed by the participants of clinicopathological conferences. The ethical and axiological aspects of the discourse under study were represented by various ways of verbal expression of its personalized nature, its values and types of reasoning.

Key words: *medical discourse, biomedical perspective, clinicopathological conference, ethical and axiological aspects.*

БИОЭТИЧЕСКИЕ АСПЕКТЫ МЕДИЦИНСКОГО ДИСКУРСА

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Проблемы изучения институционального взаимодействия участников сферы оказания медицинской помощи недостаточно изучены и требуют осмысления с позиций биоэтической парадигмы. Целью статьи явилось выявление биоэтических аспектов медицинского дискурса. В работе обосновано авторское понимание медицинского дискурса и представлена его жанровая типология. В качестве объекта изучения использовался жанр клинико-патологоанатомической конференции. Установлено, что медицинский дискурс данного типа является концентрированным выражением биомедицинской перспективы при концептуализации действительности. Наряду с биомедицинским подходом в ходе клинико-патологоанатомической конференции выявлены биоэтические принципы представления дискурсивного медицинского знания. Этико-аксиологический аспект рассматриваемого дискурса репрезентирован посредством различных способов вербального указания на его личностно ориентированный характер, ценностную и аргументативную природу.

Ключевые слова*: медицинский дискурс, биомедицинская перспектива,*