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ON BIOETHICAL COMPONENT OF PATIENT SAFETY IN SURGERY

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Priority areas in the safe treatment of surgical patients include improvement of doctor-patient communication and optimization of interaction of personnel, which successful implementation is impossible without the development and practical application of modern bioethics. The study of the communication component of the informational and legal safety of patients revealed that 18% of patients are not willing to participate actively in their treatment, relying on the choice of a doctor, who may face difficulties that cannot be solved by algorithms during the implementation of a patient's right to information in the most delicate form. The survey of 110 surgeons revealed that 39.1% of them are not familiar with the basic provisions of the Federal Law № 323-FZ, 12.7% – do not consider the problem of compliance with patient's rights to be relevant, and 55.5% of surgeons were previously involved in conflict situations with patients.

Keywords: *surgery, patient safety, bioethics, medical communications.*

О БИОЭТИЧЕСКОМ КОМПОНЕНТЕ БЕЗОПАСНОСТИ ПАЦИЕНТОВ В ХИРУРГИИ

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Одними из приоритетных направлений безопасного лечения хирургических пациентов являются: совершенствование форм общения с пациентами и оптимизация взаимодействия персонала, успешная реализация которых невозможна без развития и практического применения достижений современной биоэтики. При изучении коммуникационного компонента информационной и правовой безопасности пациентов оказалось, что 18% из них не желают активно участвовать в процессе собственного лечения, полагаясь на выбор врача, перед которым, при реализации права пациента на получение информации в максимально деликатной форме, возникают трудности, не поддающиеся алгоритмированию. В результате анкетирования 110 хирургов выяснилось, что 39,1% из них не знакомы с основными положениями 323 ФЗ, 12,7% – не считают актуальной проблему соблюдения прав пациента, при этом 55,5% хирургов ранее были фигурантами конфликтных ситуаций с пациентами.

Ключевые слова: *хирургия, безопасность пациентов, биоэтика, медицинские коммуникации.*

Patient safety (PS) is a major global health problem, because health professionals have to provide medical care to patients under a multi-vector pressure and in a rapidly changing environment [9, 12]. In the case of the most modern, technologically organized treatment, the risk of adverse, although sometimes highly probable, events, adverse outcomes of treatment and conflicts is not just possible, but inevitable [12, 14].

PS is a branch of modern medicine and health policy that is supported at the global level by the World Alliance for the patient safety of WHO, which is responsible for monitoring and analysis of the negative effects of the treatment or the use of medicines and medical technologies [1, 8, 9, 13, 14]. Despite the development of information and medical technologies, the recent studies have found that the risk of adverse effects and adverse reactions increased with time, leading to the fact that the health of every tenth patient in the developed countries is harmed during treatment in hospital [9, 12].

According to the meta-analysis carried out by E.N. de Vries et al. [8] based on the results of the study of over 74 thousand treatment episodes, the average frequency of adverse outcomes was 9.2%, while an average probability of preventable complications was 43.5%. Although, 56.3% of these cases had minor effects on patients, 7.4% – resulted in death.

Since domestic health law regulatory documents do not define PS, most experts equate the safety of care to its quality. According to paragraph 21 of Article 2 of the Federal Law No.323, dated November 21, 2011 "On the fundamentals of public health protection in the Russian Federation", *quality of care is a set of characteristics that reflect the timeliness of care, correct choice of approaches to prevention, diagnosis, treatment and rehabilitation in medical care, and degree of achievement of the planned results* [6].

The problem of adverse events in medicine is not new. While foreign countries have been accumulating actual evidence base on this issue since the early 1990s [8, 9, 14], improvement of our national health care must take into account the need for more intensive scientific research and the most rapid implementation of their positive results in the area of medical practice.

Results of further research have led to the most important political debate and public discussions on the issue of PS in the world; however, they cease these days, because adverse events contribute significantly to increasing financial burden on the society [9, 10, 12].

The modern concept of ensuring PS assigns the responsibility for adverse events primarily on the structural, organizational and operational deficiencies of the health system or health-care products, rather than on individual health care workers, because the majority of adverse events are not the result of negligence or poor training of medical personnel, but latent systemic causes [7, 8, 12].

Conceptually, improvement of PS requires:

- Development of opportunities for learning from mistakes through improved reporting systems, investigation of incidents and responsible dissemination of findings;
- Development of opportunities for the prediction of possible errors and detection of latent systemic weaknesses that might lead to unintended consequences;
- Identification of available sources of knowledge, both in health care and in other sectors;
- Improvement of the system for the provision of medical assistance for proper restructuring of services and departments, reorientation of incentives and transformation of quality into the core foundation of the entire system. In general, all national programs are based on these principles [1, 13].

Today, there are insufficient grounds to postulate the priority models for the safety of surgical patients. To find an optimal solution to this strategic issue, a number of studies focused on the role of doctors [12], other studies focused on the role of nurses [7], as well as analysis of organizational and structural factors [13].

If the analysis of the national systems for safety of treatment of surgical patients revealed significant differences in the priorities of the organization of activities in areas [13, 14], than basic activities for organization of PS in surgery at the level of medical facilities should include:

- Improving forms of communication with patients;
- Optimization of interaction between personnel;
- Identification of patient’s identity;
- Assessment of the risk of dangerous situations;
- Prevention of falls of patients;
- Prevention of pressure sores;
- Prevention of infections associated with health care;
- Prevention of venous thromboembolic events;
- Safety of pharmacotherapy;
- Prevention of surgical interventions with erroneous localization;
- Prevention of fire in operating rooms.

Successful implementation of the first two items from the above list is not possible without the development and practical applications of modern bioethics, since the improvement of communication technologies in rendering medical care is an important part of the overall strategy of the modern medical process that is enshrined in the patients’ rights in national and international legal and ethical regulations and codes [13].

Prerequisites for effective communication between members of the treatment process are completeness of the information, its accuracy, timeliness, unambiguity, and most importantly its clarity for a patient [1]. It is appropriate to point out that even within the concept of personalized medicine, the influence of social and psychological situation of an individual patient on the effectiveness, and thus the safety of treatment, is taken into account, but it is not a subject of intense professional interest of health care workers [3, 5].

In this regard, the results of the study of outcomes of surgical treatment in patients with racial differences are quite interesting from a bioethical point of view. It has long been known that in the United States among African Americans, as compared with the White Americans, the objective indicators, such as the incidence of postoperative complications and mortality [10], and mortality for sepsis [11], are higher. However, it is difficult to explain with the objective criteria why African Americans have a much higher level of personal dissatisfaction with the quality of care provided to them; moreover, the majority of the data showed that doctors fail to get the symmetrical response due to the shortage of daily communication with patients [9, 14]. These and other reasons determine the fact that the problem of relations between health professionals and patients in the process of health care rendering does not lose its relevance today and is discussed by lawyers, health care managers and clinicians around the world. It is encouraging to note that thanks to the efforts of Russian researchers, this process is developing quite dynamically in our country, with constant readiness to quickly and convincingly respond to changes in legal, ethical and scientific space [2, 3, 4].

Discussion of all aspects of treatment, care and medical service with patients and their families is an important part of the treatment process safety culture; it is no secret that when patients become active participants in their own treatment, they are more likely to be concerned about complications [1]. Majority of health care professionals spend their entire professional life improving their technical, tactical skills and analytical abilities, continuously expanding basic and current information arsenal. However, equally important professional quality, which helps to minimize or greatly reduce the risk of conflicts, and thus increase the safety of both a patient and a doctor, is a perfect form of communication with patients and their families. At the same time, it is not always possible to achieve an identical assessment of the quality of communication and understanding from both sides of the treatment process.

We support the view that the improvement of professional skills and qualities of health care workers is possible only on the basis of educational programs, which development took into account the real problems of the regional professional association of medical professionals or an individual institution that were identified as a result of prior, well-designed scientific studies.

With respect to the problem discussed in this work, assuming that different patients are likely to have different possibilities, desire and the degree of motivation for their personal involvement in their own treatment, we conducted a population-based study, which had an ultimate goal – improving the communication component of informational and legal PS. We conducted a survey of 144 patients of Non-governmental healthcare institution “Railway Hospital at the station Vladikavkaz” JSC Russian Railways in 2014.

Respondents were offered a questionnaire with the following content (*style of the original was saved*):

1. **What doctor-patient interaction model do you prefer?**

Paternalistic model (from Lat. Pater - father), when a doctor decides all medical issues for a patient, including how much information a patient “should” know about his/her health status. Restrictions for patient information are determined by good intentions to protect the patient from “harmful” information, and the patient has full confidence in the choice of the doctor.

Information model, which is based on the rule of informed consent, enshrined in the Federal Law No.323 on the fundamentals of protection of public health in the Russian Federation (323 FZ) that is being in force since January 01, 2012 [6]:

Article 22. Health status information.

Everyone has the right to receive information about health status in the available form from medical organizations, including information about the results of medical examinations, presence of diseases, disease diagnosis and prognosis, methods of care, associated risks, possible forms of medical intervention, its consequences and results of health care provision.

Health status information cannot be given to a patient against his/her will. In case of unfavorable disease prognosis, information should be communicated in a delicate form to a patient, or husband/wife, someone of the relatives, if the patient did not forbid to inform them and (or) did not define a person who can receive such information.

2. **Specify how you understand the expression** … *available form of information*?

3. **Specify in your own words how you understand** acceptable *form of determination of your will to be informed*?

As a result, 18% of patients prefer to rely on the choice of the doctor in their treatment as for the methods of examination and treatment. The majority (82%) of patients accept active approach in addressing the key issues of their own treatment. The conclusion is ambiguous, since almost every fifth patient requires an approach to the implementation of the right to information about health and all related details, which differs from current legislation in the field of health.

The following answers were received for question about the preferences of patients as for available form of information (*original edition was saved as far as possible*):

- Only personally and in full – 73%;
- Through relatives – 9%;
- In a delicate, gentle manner – 9%;

- In plain language, without unnecessary use of medical terms – 9%.

The following answers were received for question about the form of determination of the will of patients to receive information:

- Verbally– 28%;
- In writing and during communication only with an attending physician – 54%;
- Voluntarily (?) – 9%;
- This should depend on the condition of a patient to receive the information (?) – 9%.

When choosing the form of communication of medical information to a patient, a doctor does not experience significant problems. The information should be reported to the patient in a delicate form that is understandable to people without medical education. Given this approach, the majority of our patients (91%) are ready to make decisions on key issues of the treatment process, and only 9% fully rest responsibility upon their relatives.

Doctors face a much more difficult task when they first (preferably in the most delicate way) have to find out the patient's will, as formulated in the Federal Law 323. This task is facilitated if a patient trusts the information about his/her health to relatives when giving informed consent; otherwise, there is none perfect solution, especially in unfavorable prognosis of the disease as in the case of cancer. Moreover, judging by the responses of our patients, about one-fifth of them either did not understand the question or did not know a definite answer, otherwise it is difficult to estimate received strange answers marked with (?).

To assess the state of professional awareness of surgeons, as well as to determine the extent of the practical implementation of the legal component of PS in surgery, we performed a multicenter study, which design was approved by the ethics committee of North Ossetian State Medical Academy (Protocol No.46 as of October 30, 2014). We obtained information on professional competence of 110 practicing surgeons in the field of legal and informational foundations of PS, using 50 questions within the legal block.

Result: the WHO program "On patient safety" was known to only 51% of respondents, and the concept "Safe Surgery Saves Lives" was known only to 55% of surgeons. Only 60.9% of surgeons were familiar with the basic provisions of the Federal Law 323 "On the foundation of public health protection in the Russian Federation", and only 1.8% of doctors always have it at hand, despite the fact that 55.5 % of surgeons were involved earlier in conflicts with patients in their practical work.

One of questions on the questionnaire was formulated very simply: "Do you consider the compliance with the patients' rights to be relevant?" Initially, when preparing the list of questions, we considered the possibility to exclude this question, because we predicted unambiguous answers. However, it was found that 12.7% of practicing surgeons do not consider the problem of compliance with patients' rights to be relevant and do not consider it necessary to make any changes in their communication strategy within the treatment process.

Conclusion

Nowadays, the doctor should first remember that the patient is at risk of adverse outcomes because of the treatment process.

Safety is a fundamental principle of treating patients and a critical component of health care quality management. A major task of a doctor, among a number of other less significant consequences for a patient, should involve minimization of risks of occurrence and timely removal of adverse outcomes of treatment.

Confidence that adverse events in the treatment of patients are pre-determined or provoked by non-adjustable systemic factors that do not depend on us limits the possibility to learn from mistakes.

Modern measures that ensure the safety of surgical patients should cover almost all medical profiles and all participants of the system, and its bioethical component is an essential component of the modern level of organization of the treatment process.

Continuous improvement of communication strategies should be implemented by all participants of the treatment process, based on targeted educational programs developed taking into account the interests of all subjects of medical law.

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