LEGAL AND ETHICAL ISSUES OF ESTABLISHING THE BOUNDARIES OF INFORMED CONSENT

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The article deals with legal and ethical issues of establishing the boundaries of informed consent as a basic procedure being an integral part of medical practice, biomedical and clinical human research, and a broad list of medical procedures. A comparative analysis was based on examination of the best global models of informed consent. In the future, their implementation into the Russian legislative and regulatory compliance practices is suggested. The research uses the following methods: analysis and synthesis, analogy, method of legal modelling, and method of comparative legal research. Some conclusions were made about the reception of certain legal issues considering such factors as legal mental structure, level of legal culture, etc. In this article, the following aspects are highlighted: requirement for information disclosure, requirement to understand the relationship, a researcher's liability to enhance qualifications, a patient's responsibility, and the issue about an informed consent form.

Keywords: voluntary informed consent, boundaries, legal and ethical issues, legislation

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ПРАВОВЫЕ И ЭТИЧЕСКИЕ ПРОБЛЕМЫ УСТАНОВЛЕНИЯ ГРАНИЦ ИНФОРМИРОВАННОГО СОГЛАСИЯ

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В статье рассматриваются правовые и этические проблемы установления границ информированного согласия как базовой процедуры, являющейся неотъемлемой частью медицинской практики, биомедицинских и клинических исследований с участием человека, а также широкого перечня медицинских процедур. Сравнительный анализ проведен на основе изучения лучших мировых моделей информированного согласия. В перспективе предполагается их внедрение в отечественную законодательную и правоприменительную практику. В исследовании использованы следующие методы: анализ и синтез, аналогия, метод правового моделирования, сравнительно-правовой метод. Сделан ряд выводов о рецепции некоторых правовых положений с учетом таких факторов, как правовой менталитет, уровень правовой культуры населения и пр. В статье освещены следующие вопросы: требование о раскрытии информации и требование о понимании их соотношения, обязанность исследователя совершенствовать свой профессиональный опыт, обязанности пациента, вопрос о форме информированного согласия.

Ключевые слова: добровольное информированное согласие, границы, правовые и этические проблемы, законодательство

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While obtaining voluntary informed consent, one of the most important issues includes establishing the boundaries of such consent — the data, situations and circumstances not covered by it or the situations that exclude obtaining such consent. It should be mentioned that the limitations are normally classified into legal and ethical ones. Ethical requirements are the most complex ones to be complied with. They are currently the least developed in the Russian legal practice. However, legal support of the issue in Russia leaves much to be desired as well.

It would thus be logical to call upon foreign expertise. But to do this, it is necessary to take into account typical features of the Russian legal regulation, legal mental structure and conservative strategy adhered by Russia with regard to biotechnology implementation, reception of law and adaptation of legislation due to accelerated development of innovative technologies in medicine. Note that legal regulation of the mentioned issues abroad depends on the established system of national and international legal instruments.

Moreover, defining the term 'informed consent' and its practical implementation are significantly different due to two main approaches:

a) This is an instrument with all required data about a patient and data for information such as adverse effects, contraindications or concomitant diseases a doctor must be informed of prior to therapy;
b) This a doctor-patient communication process when the entire necessary information and preliminary consultation are obtained, alternative treatment options are selected,

risks and advantages are assessed, etc. and which finally produces an influence on whether a patient's/participant's informed consent is provided or not.

MATERIALS AND METHODS

Certain universal scientific research methods were used throughout the study. They included analysis and synthesis to find similarities and differences regarding the way the term and boundaries of the informed consent are comprehended; reflecting the abovementioned issues from the standpoint of medical ethics, and differences in legal regulation based on social, economic and mental factors; ways to improve the informed consent form, and development of consent typology depending on the type and purposes of treatment/medical intervention.

The need for using the method of legal modelling is implied from the above. The use of two private scientific methods — technically legal and hermeneutic methods — is absolutely essential as they enable complex estimation of the set issue legal constituent. During the research, the axiological approach was utilized, as three sciences — ethics, medicine and law — share their interests in the issue.

Nevertheless, the method of comparative legal research is the basic method used to study the informed consent institute abroad.

RESEARCH METHODS

Information disclosure: main approaches to fulfilling the requirement

In accordance with the standard approach, the requirement for information disclosure is similar to that of how a patient/client comprehends the information [1]. In particular, this position is reflected in basic international documents on research ethics. Based on article 1 of the Nuremberg Code,' a person who provides consent should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision' [2].

The Declaration of Helsinki states as follows with the regard to the procedure of data disclosure: 'In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and post-study health outcomes' [3]. Particular attention should be paid to the way the information is presented, as unlike young people, elderly usually require more detailed, simple, slow and clear explanations.

The Guideline of the Council for International Organizations of Medical Sciences (CIOMS) [4] contains 26 requirements for obtaining informed consent and 9 other specific requirements for the contents of the document. As far as information goes, it is stated as follows: 'Researchers should apply real-world data to transfer information and ensure its comprehension'.

With respect to the national legislation, the Belmont Report should be consulted. It provides that 'researchers have the responsibility to accurately establish the adequate data perception by a subject' [5].

The term 'adequate' is thus determined in every particular case. It is expected, however, that a subject has a certain level of comprehension. Possible risks can include the most common and serious consequences occurring during or after the research. Moreover, according to article 26 of the Declaration of Helsinki, 'the potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal' [6].

The explanatory work should always precede giving informed consent. In its content, the consent should correspond to the explanation. The 'concept' [7] restores the balance in doctor-patient relationship with simultaneous provision of connection between them: a doctor concentrates on treatment being free to take decisions, whereas a patient remains a master of his own body and health and can refuse from being treated by the doctor at any time.

It could not be established without a doubt that in Russian legal reality, informed consent is an integral legal concept because according to the author, the term primarily means compulsory compliance with the requirements. The requirements do not constitute a concept but serve as elements of obtaining consent and ensure its acceptability for subsequent studies. It is the lack of a clear single concept as an integrity of a doctor's — and especially of a patient'- rights and responsibilities and mutual responsibility that gives birth to the mentioned ethical and legal dilemmas.

Unfortunately, the Russian legal literature fails giving due attention to explanation as the central element of informed consent. Thus, it is appropriate to recall upon the experience of other countries.

According to another approach, requirements for information disclosure and comprehension have principally different etiologies describing the cases when obtaining consent can be declared null and void [8].

The primary aim of information disclosure is not to reach an understanding, but to avoid illegitimate control. For this, a subject requesting consent should share all available information which is associated with the consent-related decision by the subject and which is reasonably expected to be gained by the subject providing the consent [9].

The requirement for comprehension is based on conditions for successful oral consent. For the consent to be successful, a subject who gives the consent should understand:

1) that he/she provides the consent;
2) how to use the right to provide or withdraw the consent;
3) what exactly he/she gives the consent for [10].

Requirement for comprehension: various opinions

According to the point of view about the subjective interests, the prerequisite of valid consent is that a subject who gives the consent comprehends all true (valid) suggestions about the study associated with the subject's interests. For instance, a potential participant must be aware of serious potential side effects of medications, because the side effects are related to compliance with and protection of the interests [11]. There are some illustrative examples that show the need of compliance with this requirement.

The first case considers an 18-year-old patient with mild ornithine transcarbamylase (OTC) deficiency, a rare hepatic disease, controlled with medicines and strict diet [12].

According to the patient's father, the patient provided a voluntary consent to participate in the innovative federal study of gene therapy because he was informed of low risks. However, researchers were aware of the fact that large doses of the gene medicine were toxic for animals. Cerebral death occurred four days after the injection. The researchers stopped the study. An initiated investigation resulted in governmental sanctions and judicial proceedings. During the civil trial, the plaintiffs claimed

that a lack of informed consent associated with the lack of data about previous unfavorable animal experiments and undisclosed direct financial incentives of the leading researcher facilitated out-of-court dispute resolution [13].

Quite frequent cases of children's compulsory vaccination by parents who rely on the doctor's experience and who are not interested in possible adverse effects are even more indicative. Data on adverse events from vaccination are available on the website of the Ministry of Health of the Russian Federation in small print. It is stated there that the percentage of adverse effects is small but they are rather serious and can even result in autism. Thus, the text should be mandatory reading. This is useful to determine whether subjects have sufficient knowledge not to refuse from their rights, but to make an informed decision about the participation. The more we are aware of what is raising difficulties in real participants, the better we are prepared for developing the process of obtaining consent for future participants.

Responsibility to have a professional experience

Researchers fail to perform another professional duty: responsibility to acquire and support the experience in their field of specialization. Just as a doctor has to work to keep up on medical affairs that are relevant to the patients, so a researcher needs to be aware of the latest achievements in his field of research. This is essential both for research participants, and for the quality of scientific results. Though the fact has hardly been mentioned, it is still a distinctive feature of good researchers [14].

Informed consent forms are frequently of a similar structure. They are stuffed with complex legal wording and institutional forms of protection, and commonly have several pages of complicated terms and explanations in small print. Many people sign these forms without going into details [15].

Responsibility of a patient posed by informed consent

There exist at least four rationales that make a patient much more responsible for implementation of the tasks: an epistemic, a deontological and two conceptual ones.

The epistemic rationale is based on two simple observations. They state that many changes in the way of life desirable to promote health are rather difficult to be implemented in reality and that doctors sometimes are not aware of how they are difficult for a certain patient.

The deontological rationale is directly based on the epistemic one. Responsibility towards the truth is mentioned rather frequently. Violation of this rationale is considered especially serious when a person is blamed for something he/she didn't do. As a rule, doctors don't know whether patients made every effort to, say, decrease their weight. The uncertainty is a sufficient rationale not to blame such patients for what they haven't done.

The first rationale relates to an ability of patients to change an unhealthy way of life. There are reasons to believe that chances of success are higher if patients set a goal and if they are encouraged to believe in their success [16]. So, if a doctor places responsibility for performing (a task) on a patient and lays emphasis on possible achievement of success, a positive effect can be expected.

The second rationale is about direct relationship between liability for fault and mental condition of a patient. There is some evidence that patients suffer when they are told that they are responsible for the existing disease. Other researches confirm that patients who blame themselves for the disease and believe that it is developed because of their drug-associated behavior have an increased risk of negative consequences for mental health such as depression [17]. In conclusion, it should be noted that people's sufferings can be strengthened by making them believe that it is all their fault. Obviously, it is an important reason not no transfer the messages [18].

Specific proposals aimed at a patient's better responsibility include agreements where a patient agrees with certain conditions of doctor-patient relationships such as a timely visit to a doctor, taking prescribed medications, clearance of arising issues and informing a doctor of the noted symptoms. Some hospitals issue the lists when drawing up documents for inpatients.

The American Medical Association has issued a detailed list of a patient's obligations including the ones to take preventive health promoting measures [19]. Standard suggested formulations state as follows: 'to provide the best possible case' or 'implement the purposes of taking care about your health'. There is no mention (at least printed one) of punishments or consequences faced if a patient fails to fulfill the obligations.

The status of similar lists and agreements is unclear. Unlike it happens after signing the informed consent form, violation of a patient's promise to take the prescribed medications and follow the recommended diet doesn't represent any moral or legal basis for treatment refusal or discharge from hospital. What if such contracts acquire the same moral and legal status as an informed consent form? Non-fulfillment of a doctor's responsibilities implies tangible consequences. The doctor can be reprimanded, deprived of a license, dismissed or subjected to prosecution. Even if none of this happens, the doctor can lose patients' trust because of bad feedback.

Informed consent form

It is not specified in legislation of many countries, including the Russian Federation [20] and the Federal Republic of Germany. In Germany, they basically use a written form while performing a surgery. There is differentiation between an abstract form (consent for a certain intervention with blank space where the risks are described by the doctor) and a specific brochure that contains non-fiction text about this intervention. Besides, the doctor interviews the patient who can ask questions.

In Poland, there exist two forms of consent in medical law: a standard or given in a written form. The first one means a verbal or implied consent which gives rise to no doubts. The written form must be given in a positive and preliminary way. The law of Poland regulates situations, in which minors, incapable or other persons are involved; it also differentiates between the types of medical interventions that require compulsory provision of consent in writing [21].

In spite of thorough legal discussion, the concept of explanation and consent is limited by the humanistic principle in which a doctor's commandment of causing no harm should be taken into account during an explanation of a fatal diagnosis. In some cases, it means that the diagnoses should be willfully concealed.

There are *three types* of such situations:

- mental contraindications;
- possible increase of risk, for instance, in case of a heart disease, understanding the data can result in infarction;
- endangering other persons, for instance, in case of a mental disease, diagnosis reporting can result in increased aggression against close relatives.

CONCLUSIONS

To sum up, it should be noted that in spite of abundance of legal models that consolidate different aspects of informed consent, none of them was considered by a Russian legislator while legislation improvement. This is a mere omission. Nevertheless, there exist ways to implement positive and informative foreign experience into the Russian system of legislation.

First and foremost, this includes establishment of a general guideline for effective support of informed consent obtaining. In Russia, attempts were made — to no avail yet — to create the ethical code. Moreover, it was supposed to be a single unified document consolidating the ethical issues of clinical research, personalized medicine, genetic research, genome registration, passporting and other similar issues that would definitely arise due to development of technologies and new trends in research. But this is not sufficient and the document would probably be hard to implement. The reason can include a large scope of proposals and lack of real ability for their implementation. It would be more effective to create separate brief and broad documents for the most complex and challenging fixed points — informed consent being one of them — with their subsequent implementation into medical practice. In this case, a necessity in formulating numerous blanket and reference rules ceases to exist. In the documents, it's required to consider the basic essential principles created in the image of the Belmont Report and key aspects of fulfilling the requirements, develop a typology of consent forms depending on the area of their application. Moreover, it is necessary to lay down the rights and obligations of every party in detail. In our opinion, the documents will improve the acting federal laws and legislative instruments in a more simplified and rapid way.

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