INFORMED CONSENT IN RUSSIA: MISUSE AND ABUSE

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Even T. Beauchamp and J. Childress, the founders of ethical principlism, noted that in practice the principles of bioethics, which they might have formulated, may conflict, and adherence to one principle may violate the other. To date, the conflict between the principle of autonomy and the doctrine of informed consent, and the principle of vulnerability formulated ten years later (one of the principles introduced by P. Kemp) and the necessity to take care of the patient is one of the major irreconcilable conflicts. This conflict is especially severe in Russia, where the informed consent was immediately enshrined as a statutory provision without prior discussion with the medical and non-medical communities, which gave rise to numerous opportunities for misuse and abuse, and stepped up the bureaucratic pressure both on patients, who became more vulnerable, and the physicians, who started using the informed consent to their advantage, sometimes being openly market-oriented. The growth of mutual mistrust, sometimes reaching the level of aggression, forces one to find a remedy for this situation. In the author's view, this requires revision of the patient's autonomy concept and the concept of informed consent considering the acceptance of the patient's intense vulnerability and the patient's need for the healthcare specialists' (physicians and nurses) personal involvement and care. It may be helpful to consult the writings of the ethics of care, feminist ethics and other ethical trends representation, as well as the results of field research aimed to combine principles of freedom and patient care in a given situation.

Keywords: informed consent, principle of autonomy, ethics of choice, principle of vulnerability, ethics of care

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ИНФОРМИРОВАННОЕ СОГЛАСИЕ В РОССИИ: ИСКАЖЕНИЯ И ЗЛОУПОТРЕБЛЕНИЯ

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Еще основатели этического принципализма T. Beauchamp и J. Childress отмечали, что сформулированные ими принципы биоэтики на практике могут вступать в противоречие, когда следование одному из них нарушает другой. Одно из наиболее непримиримых противоречий на сегодня — между принципом автономии и правилом информированного согласия и сформулированным десятилетием позже принципом уязвимости (один из принципов П. Кемпа) и необходимостью заботы о пациенте. Особенно остро это противоречие проявляется в России, где, без предварительного обсуждения медицинской и немедицинской общественностью, информированное согласие сразу было закреплено в качестве законодательной нормы, что породило массу злоупотреблений и искажений, усилило бюрократическое давление как на пациентов, сделав их еще более уязвимыми, так и на врачей, которые стали использовать информированное согласие в своих, иногда откровенно рыночных, интересах. Рост взаимного недоверия, которое иногда доходит до проявлений агрессивности, заставляет искать выход из сложившейся ситуации, который, с точки зрения автора, требует пересмотра концепции автономии пациента и информированного согласия с учетом признания глубокой уязвимости пациента и его потребности в неравнодушии и заботе со стороны медицинских работников — врачей и медицинских сестер. Здесь может помочь знакомство с трудами представителей этики заботы, феминистической этики и других этических направлений, а также с результатами «полевых» исследований, в ходе которых делается попытка в каждой конкретной ситуации совместить принцип свободы и заботу о пациенте.

Ключевые слова: информированное согласие, принцип автономии, этика выбора, принцип уязвимости, этика заботы

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Preface

As a lecturer in bioethics, the author has an opportunity to ask the trainees, i.e., students, postgraduate students, physicians and nurses, about their interpretation of the informed consent rationale: whose rights are protected by this process? The vast majority give an emphatic response without hesitation: the interests of physician (nurse). And then they explain: the patients should be responsible for their decisions, the physician is not a nanny for his patient, etc. It seems that many modern physicians sort of forgot, or, may be, did not even know, that the informed consent was set up to protect the patient against high-handedness of the medical specialists and was considered the greatest achievement for the protection of human rights. They don't realize that the use of informed consent for the benefit of physicians may give rise for numerous opportunities for misuse and abuse, which quite often violate the rights of the patients for protection of whom the informed consent has once been invented. What are the reasons for such misperception, and what are the prospects for the informed consent within the framework of healthcare system in Russia?

Historical background of the informed consent, Russia (1924)

The world's first requirement for the patient's consent to surgery was laid down by the Decree of the All-Russian Central Executive Committee and the RSFSR's Council of People's Commissars "On Professional Work and the Rights of Medical Specialists" issued on December 1, 1924. Article 20 of the Decree stated: "*surgical procedures are performed with the patient's consent, and in individuals under the age of 16 and mentally ill patients these are performed with the consent obtained from their parents or guardians. Immediate surgery, essential to save the life or the important organ, may be performed by the doctor after a consultation with the other doctor without the consent of*

a parent or guardian, in case they cannot be asked without risk of being late, and without patient's consent in case the patient is unconscious. Given the consultation involves a risk of being late, the doctor can make the decision for surgery himself. He must inform the Health Board about each of these cases no later than in twenty four hours".

As shown in the text of the Decree article, the consent was applied only to surgery, no provision had been made for the consent to be documented in writing, and the question of refusal of surgery was out of consideration. However, the document was truly revolutionary and, with minor modifications, remained relevant for many decades.

In 1970–1993, the main legal instrument governing the health system performance in the USSR was the "Fundamentals of Legislation of the USSR and the Union Republics on the Health Service" dated December 19, 1969, 1 4589-VII (entered into force on June 1, 1970). Article 35 of the Fundamentals on the consent to surgery almost entirely reproduced the norms set out in the Decree issued in 1924: "*Surgical procedures are performed and advanced diagnosis methods are applied with the patient's consent, and in patients under the age of 16 and mentally ill patients these are performed or applied with the consent obtained from their parents, guardians or caregivers. Immediate surgical procedures are performed and advanced diagnosis methods are applied by doctors without the consent obtained from the patients, their parents, guardians or caregivers only in very exceptional circumstances, when the delays in diagnosis or surgical treatment threaten the life of the patient, and obtaining the consent of the above-mentioned category of persons is impossible*".

As can be seen, in the new version of the article there were still shortcomings present in the version issued in 1924, and this version of the document was valid until 1993. It had not been amended in order to reflect new perceptions of the consent being informed and voluntary. Such perceptions had also gained recognition in the American medicine and with a lag had ventured into European medicine.

Emergence of the term "informed consent" in Nuremberg. First steps of biomedical ethics in the USA. Principlism, patient autonomy and the informed consent

As is well known, the concept of the informed consent was formulated in the Nuremberg Code based on the results of the Nazi doctors trial. At first, the informed consent was applied only to human biomedical experimentation, however, ten years later it was used more and more widely by the American private healthcare, becoming the essential element of the doctor–patient relationship. Later the informed consent formed the basis of the American bioethical principlism declaring respect for the rights and freedoms of the patient. According to Tom Beauchamp and James Childress, the Founding Fathers of the novel biomedical ethics, the doctrine of the informed consent, along with the doctrines of confidentiality and truthfulness, ensured compliance with four basic principles of biomedical ethics, one of which was the patient autonomy principle (1976). When introducing new approach to ethical regulation in biomedicine, T. Beauchamp and J. Childress [1] pointed out the difficulties that might arise in case of the conflict between two or more basic principles of bioethics in certain circumstances upon attempting to make a right decision, for example between "respect for autonomy" and "non-maleficence", or "beneficence" and "justice". The researchers emphasized that the principles were not arranged in a hierarchy, and that the decision-making person had an opportunity to choose the most adequate norm to follow.

Over the years, it has become clear that in the American medicine the priority had mainly been given to the principle of supporting the patient's autonomy, as well as to informed consent making it possible to implement this principle. Autonomy refers to acknowledgement of the patient's right to hold views, to make choices and to take actions based on personal values and beliefs [1]. When implementing this principle, the physician must not only show respect for the patient's personality, but also support the patient and enhance his ability to make autonomous decisions, limiting the patient only in case his decision poses a threat to other people. No wonder such ethics was referred to as ethics of choice. Later it was set in opposition to the ethics of care, as discussed below. Private healthcare in the USA, into which the ideas of consumerism had spread, engulfing all American community experiencing the post-war economic boom, easily absorbed this particular variant of bioethical principlism with a focus on respect for the freedom of choice of the patient as the healthcare consumer.

First steps of bioethics in Europe. Criticism of American principlism. Principle of vulnerability and new approach to informed consent

European bioethics was 10–15 years behind the American bioethics. It was a short period. However, it was long enough to understand that disparities between the principles of "respect for autonomy" and "beneficence" might be irreconcilable. European humanism with the concept of social solidarity was unable to fully accept American ethics of choice. European specialists in bioethics often give a negative answer to a question "how "moral" are the principles of biomedical ethics" introduced by T. Beauchamp and J. Childress (Marcus Christen et al, 2014). [2]. While acknowledging the imperfections of the four principles of American bioethics, without departing from principalism, European bioethics introduced the different set of basic principles: principles of respect for autonomy, dignity, integrity and vulnerability. When speaking of autonomy, European bioethics gave this concept a new interpretation with a focus on personal freedom in the broadest sense of the term, without limiting it to the right to choose. At the same time, great importance was attached to the principle of patient's vulnerability, underpinning the environment of patient powerlessness and dependency, and justifying the moral responsibility of fellow man to take care of those who are unable to care about themselves. Thus, in the dispute between the right to choose and the right to care European bioethics made care a priority. That is how the conflict between two approaches to ethical regulation in biomedicine emerged, the conflict between ethics of choice and ethics of care.

The conflict of those expanded across the interpretation of the informed consent. European ethics of care does not deny the doctrine of the informed consent, however, the interpretation is different. The doctrine is considered not the need to ensure conditions allowing the patient to make a free and responsible choice, but helping the patient to find the acceptable way to recovery (reducing suffering, improving the quality of life), which is consistent with the patient's values and abilities. This approach requires not just awareness-raising, but quality empathic interpersonal interaction between the patient and the physician. In this approach the proponents of the ethics of choice see the signs of the condemned paternalism, which deprives patient of his liberty. However, they completely miss the point, that formal informed consent process is often accompanied by total indifference to patient. There is a problem

that is "*not that others are trying to command you, but that no one cares about you*". (Annemarie Mol, 2008) [3]. According to the ethics of care logic, the informed consent may be an act of caring about somebody, as natural as reaching out hands to a person, who has fallen in the street, in order to support. It is worth emphasizing that debates over two approaches to solving the problems of morality in medicine continue to this day.

Informed consent in Russia. Legal acts issued in 1993 and 2011

But let us return to Russia, where in 1993, in a wave of perestroika, the new "*Fundamentals of the Legislation of the Russian Federation on Health Protection*" were adopted. The adoption of those provided a legislative basis for the Russian healthcare transition to a market economy. Medical care turned into a service, the physician became a service provider, and the patient transformed into a client. The doctor–patient relationship was equated to buyer–seller relationship to be covered by the consumer law. Under such circumstances the informed consent was placed in the context of transaction for supply of services between two parties: the service provider was obliged to inform the client about the salient attributes of the service and had no right to impose the service. It was this ideology that was embedded in Article 32 of the Fundamentals, which stated the following: "The person's informed voluntary consent is the requisite preliminary condition for medical intervention". The next 33rd Article of the Fundamentals gave an explanation: "a person or his legal representative shall have the right to refuse the medical intervention or to demand its termination", and "if a person or his or her representative renounces medical intervention, then possible consequences of this decision shall be explained to them in an understandable form". Article 34 permitted providing medical care without the consent "in cases of patients who suffer from contagious diseases and serious psychic disorders or for persons who have committed socially dangerous deeds on the grounds and in the order prescribed by the legislation of the Russian Federation".

Even the cursory glance at the 1993 law made it clear that the law was based on the American bioethical principlism, i.e. the concept based on the development of principles, when the major treasure for the physician was the patient's (consumer's) right to choose freely rather than the patient's well-being. Without being reflected by society in the field of bioethics, these principles were immediately enshrined in the law. It is worth emphasizing that this approach came in some ways as a surprise both for Russian physicians and Russian patients, and the further application of the practice of the informed consent in our country resulted neither from the patients' perceived need for autonomy, nor from the physicians' understanding of their responsibility for implementation of this patient's right. Both patients and physicians passively obeyed the necessity dictated by the law under rather tough administrative pressure. Currently, a checklist of any public auditor contains a section on ensuring respect for patients' rights, in which, for instance, the process of obtaining the informed consent from the patients is verified. Violations of provisions in this section are considered grave violations of the licensing requirements with attendant legal consequences, and constitute a cause for institution of proceedings for administrative offences. An example of judicial ruling is given below.

The female patient with paratonsillar abscess was transported to the hospital ER by ambulance. When examining the abscess, the admitting otolaryngologist saw no abscess and established the diagnosis of lacunar tonsillitis. The febrile patient was transferred to the infectious diseases hospital, where she was provided the necessary assistance. This situation somehow attracted the attention of the inspection bodies, which found out that after examining the patient the physician failed to arrange the medical history properly, and "in violation of the requirements of Article 20 of the Federal Law 1 323-ФЗ, when examining the patient, the admitting otolaryngologist did not obtain the informed consent to healthcare intervention (i.e. to examination — author's note). Under these circumstances, the admitting otolaryngologist was subject to administrative proceedings under part 3, Article 19.20 Code of Administrative Offences of the Russian Federation in the form of fine» (from the ruling of the Samara Regional Court 1 4a-847/2013 dated November 20, 2013).

Fortunately, our law does not equate provision of medical care without informed consent to violence, in contrast to some states of the USA. However, lack of proper informed consent may by treated by the court as evidence of the physician's under- or non-performance, which is necessary to find him guilty of infliction of injury or the patient's death.

Development of practice of the informed consent under such circumstances resulted in gross distortion of its meaning and in flagrant abuse by healthcare specialists. Adoption of new "Fundamentals of Health Protection of the Citizens in the Russian Federation" in 2011 in order to specify the essential amount of information provided to patient together with the formal characteristics of the consent presentation in the medical documentation, as well as to permit the provision of emergency medical care without patient's consent, did not change the big picture.

What kind of misuse and abuse are we talking about? The epigraph to this part of our paper could be the famous line from the Ivan Krylov's fable "The Wolf and the Lamb": "Always are the weak at fault before the strong". And in fact, the physicians, being the stronger party in the relationship with the patients, quickly discovered the potential of the informed consent process in protecting the physicians' rights. They managed to apportion heavy burden of weighting the risk-benefit ratio and deciding medical intervention to the patient. In the hands of physicians, the informed consent, initially intended to protect the patient against the doctors' high handedness, transformed into the need to make a responsible choice at the worst possible time, when the patient, sick and scared, confused and subservient, was very acutely aware of his or her vulnerability. The situation of shared responsibility arose: "I have already told you about the possible consequences, but it is you who have chosen this surgical procedure…"

The situation was also exacerbated by the fact, that the physician, "tempted by the market" and acting as a service provider, had learned data manipulation in order to sell something that benefits and refuse to sell something that yields losses. In this regard, the appeal to "present and future patients" of oncology clinics is significant. It was posted on Facebook business page in 2018 by Mikhail Laskov, head of the oncology clinic. V. L. Lekhtsier had found the online appeal and quoted it in his paper "Logic of care versus logic of choice in modern concepts of medical practice" (2019) [4]. So, M. Laskov addresses the patients in the following way: "… both major and minor cancer surgery should have two true objectives: life extension (including recovery from cancer, if possible) and the quality of life. Neither "Not up to the challenge?", nor "we are the only ones who...", as well as "and at work..." do not automatically mean that the objectives would be achieved". He further outlines the list of "the most cynical cancer surgical procedures", compares the consent to such procedures with

"buying false hope", and encourages the patients to make decisions after weighing the pros and cons. The final line of the appeal sums up: "It is not our choice to perform surgery on a dare". This case illustrates the opportunity for profitable "selling the false hope" contrary to the patient's well-being, not violating the patient's right to choose freely.

Physicians, having neglected the truth they were taught since their student days, that in wounded winners the wounds heal faster than in wounded losers, have started, quite relentlessly, to inform the patients about the risks of proposed medical interventions in order to avoid claims. The patients are terrified by the informed consent forms, often consisting of several pages with fine print and full of unclear terms. One female patient said: "I got the impression that I had to sentence myself to death". There are tragic cases where patients failed to stand an emotional blow after being informed about the upcoming intervention (sad story about the death of Y. Yevstigneev, who suddenly passed away after being informed about the high risk of the upcoming surgery by the cardiac surgeon).

We have found another example of the informed consent abuse in "The Diary of a Hospital Security Guard" by Oleg Pavlov, the winner of the Booker Prize [5]. While working at the ER of one of Moscow's hospitals as a security guard, the future writer witnessed the situation directly related to informed consent.

A guy with wet gangrene… His wife and son were there with him, later the oldest pulled up. He was told that leg needed to be amputated, but he refused. He was decent to look at; but it seemed that he had put himself in this situation on his own. He was one of those people that were afraid to do anything, he was afraid of his condition… They went home from the hospital, because they failed to convince the doctors to "just treat him". Mother was whiny and confused, having no courage. The youngest was very passionate – she tortured him, and he obeyed. The oldest arrived in his car, starting immediately to rally, shouted, started to "fix things" with the doctors, although eventually he also failed. The father was whiny quite the same, sort of mollycoddled by the gangrene… But he also shouted, and gave instructions about the infected leg: how to grab it, where to move, and how to bind. When a dressing was applied as a courtesy, he complained, that the dressing was done wrong…

This situation is a demonstration of gruesome indifference to patient, who was in fact denied medical treatment, and, let us be honest, was condemned to death. However, there is no doubt that in case someone asked the physician, if he was sure he fulfilled his medical duty in case of the patient with wet gangrene, he would answer that he certainly did. The patient refused surgery, and his refusal was submitted as appropriate. What is the problem? Meanwhile, this case is a typical example of decision making influenced by "vicious will", when experiencing pain, anxiety, and fear have a negative impact on the capacity of mentally healthy person of efficient volitional action control. The "vicious will" is a legal concept; bearing proof of the party vicious will allows the court to declare the deal insignificant. If the patient with gangrene signed both the refusal of amputation and the will, his relatives would have a chance to challenge the will in court referring to vicious will resulting from severe disorder. It's interesting that the patient's decision concerning medical intervention is not queried in a similar situation.

In this case the "refusal submitted as appropriate" freed the physician from the burden of looking after a not very nice patient (based on the description). Although, the patient could be hospitalized, anesthetized, prescribed detoxification and antibiotic therapy, bandaged, as well as comforted and one more time clearly informed about his problem and the need for amputation. But it is a long road; it is much easier to submit refusal.

However, hoping the properly submitted informed consent would protect them, the physicians do not fully understand the real role of this document in case of criminal prosecution or civil claim by the patient. Judicial practice suggests that judges often agree with the claimant, who believes that physicians have mispresented the information, which has made it impossible for the claimant to make a right decision. And if he knew the truth about the proposed intervention or the consequences of refusal, he would make an opposite decision. Some claimants claim that they were unable to understand what was said, that severe pain (shortness of breath, fear, etc.) made concentration difficult, and the physician used unclear terms. Thus, we know about the ER doctor convicted for failure to administer medical treatment, who had accepted the female patient's refusal of proposed assistance. A young woman sitting in the hallway looked strange, and the patients next to her told the physician about it. He came out of the office and asked the woman if she was ok, but heard swearing, which he considered a refusal of assistance. The physician returned to office in order to continue consultations, but two hours later he was told that there was a dead body in the ER. It was that woman, who, according to autopsy, died of severe bilateral pneumonia. Defending himself in court, the physician emphasized that he could not bend the rule of informed consent in case of the patient, who protested strongly against his intervention. The court rejected his explanation, saying, that two hours before her death of pneumonia the patient was likely to have severe hypoxia, and was unable to respond adequately to the offer of assistance.

In addition to overt misuse and abuse, the informed consent, being in most cases a purely formal process, stepped up the bureaucratic pressure on the patients. It is more and more often associated with violence, it raises the mistrust of the doctors and even aggression. In response to the request to submit the form we can hear: "Wanna have your ass well-covered?" Thus, instead of protecting his right to choose freely, the patient receives senseless (from his perspective) procedure, once more pulling him back from the physician.

To summarize, we can assume that current practice of informed consent in our country does not serve the interests of patients and medical community, and thus should be reviewed. Here we see the process of transformation of bioethical norms, which were prematurely, without preliminary deep thinking and conducting pilot studies enshrined in the law, from the "shield", protecting the patient, into "sword", bringing pain and mistrust (Wolf SM, 2004) [6]. Where do we find the ground for the necessary revision?

Modern ethics seeking the balance between the right to choose and right to care

In search for carefully managed informed consent process valid in Russia, it may be useful to study the current overseas experience. Currently, in foreign countries this specific issue is being studied: how to combine free choice and care of vulnerable patient. Not only philosophers, but also bioethical practitioners are trying to find the answer. They perform field research involving the informed consent-related ethical dilemmas, solved by medical practitioners and nurses in various clinical situations. The opinion of patients is also being studied. Moreover, the focus is on medical situations when the patient is in the most vulnerable condition and is unable to live without

assistance and support. Various combinations of choice and care in geriatrics, palliative care, at the stage of establishing diagnosis in oncology care, etc., are being studied

Thus, the paper by J. MacArtney et al, 2017, discusses the ambivalent pastoral model, involving friendly doctor–patient relationship at the stage of establishing the cancer diagnosis, allowing the patient both to choose freely and to accept care provided by the physician [7]. “When the relationship is smooth, I am ready to rely entirely on the expert’s view” – says one of the surveyed patients. The other female patient told us that after she had found out about her diagnosis, she read the articles on the Internet and the booklets given by the physician. However, she needed to discuss the issue, how the disorder would change her life, and her future. “I searched for a “nanny”, who would explain…” The paper by Swartz AK, 2018, upholding the principles of feminist bioethics, discusses the issue of interaction between the physician and the vulnerable patient, and raises the question of impermissibility of the forced autonomy, so prevalent in modern medicine, governed by “male law” [8]. Thus, we are now witnessing the birth of the concept of “relative autonomy” and “limited paternalism”, when the relativity and the limits are defined during the interpersonal interaction between the physician and the patient in every particular situation. We would like to call this concept situational ethics.

The only problem is that such concept requires the physician to expend excessive resources, and distracts his attention from solving the problems considered to be purely medical. Moreover, modern physicians are trained to solve such problems; they consider communication with the patients the onerous responsibility, which, strictly speaking, is not a responsibility, but an additional load, from which one wants to escape any way he could in order to descend into “genuine medicine”. Most of the physicians disagree to become “merry shepherds” or “careful nannies” for their patients. However, according to research, many patients look for not only free choice, but also for being “coddled” by the physician. Only time will tell how medicine will respond to such requests from the patients, who were “freed” by deprived of care. However, the growing gap of mistrust between the physicians and the patients does not allow us to procrastinate on this issue.

Conclusion

We will be witnessing reconsideration of the informed consent image, making the informed consent more humanistic in the near future. Even now the novel situational ethics is being formed, assuming that the balance between choice and care is defined during the meaningful interpersonal interaction between the physician and the patient in every particular situation. Perhaps, achieving the balance will require total reconsideration of the doctors' perceptions of their profession, accompanied by significantly stronger humanitarian component of the profession, as well as by changed organizational structure of the healthcare system, which, with a growing number of vulnerable patients (population ageing), will be supplemented by a meaningful sector of humanitarian support for the technology-intensive medical care.

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