HISTORY OF BIOMEDICAL RESEARCH IN RUSSIA: ETHICS LESSONS FOR THE FUTURE

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This work is the author's commentary on events and documents that are important for the correct interpretation of the history on bioethics and the search for a moral basis for preventing ethical catastrophes in the future. The historical memory of the Nuremberg trials and the realities of the humanitarian catastrophe of the COVID-19 pandemic certainly give a special impetus to the development of this topic. Important issue is the special editors of the journal's request to write this particular article. The reason is the author's discovery and presentation the unique and forgotten documents of extraordinary importance, as well as the strategic focus of the journal's policy on an objective presentation of the facts of national ethics / bioethics in order to form the integrity of the role and influence of Russia and to improve the quality of education in this area.

Key words: informed voluntary consent, bacteriological weapons, historical responsibility, solidarity, protection of future generations.

Autor contribusions: Kubar O. I. — study of archives and historical documents to analyze the formation and development of research ethics in Russia; comparison of historical documents of Russia on informing patients with the modern standard of ethical regulation; an ethical commentary on the case of former Japanese military personnel accused of preparing and using bacteriological weapons during the trial in the city of Khabarovsk, 1949. Assessment of the importance of the moral inevitability of punishment for the protection of future generations.

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ИСТОРИЯ БИОМЕДИЦИНСКИХ ИССЛЕДОВАНИЙ В РОССИИ: УРОКИ ЭТИКИ ДЛЯ БУДУЩЕГО

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Настоящая работа представляет собой авторский комментарий к событиям и документам, имеющим значение для корректной трактовки истории биоэтики и поиска нравственного основания для того, чтобы избежать этических катастроф в будущем. Особый импульс развитию данной темы, безусловно, предает историческая память Нюрнбергского процесса и реалии гуманитарной катастрофы пандемии COVID-19. Специальный запрос редакции журнала на подготовку этого материла, обусловлен открытием уникальных и забытых документов, представляющихся важными в контексте обсуждаемой проблемы, а также стратегическим фокусом политики журнала на объективное изложение фактов развития отечественной биоэтики с целью осознания роли и влияния России на развитие этики исследований и повышения качества образования в данной сфере.

Ключевые слова: информированное добровольное согласие, бактериологическое оружие, историческая ответственность, солидарность, защита будущих поколений.

Вклад автора: Кубарь О. И. — изучение архивов и исторических документов для анализа становления и развития этики исследований в России; сопоставление исторических документов России по информированию пациентов с современным стандартом этического регулирования; этический комментарий по делу бывших военнослужащих японской армии, обвиняемых в подготовке и применении бактериологического оружия в ходе судебного процесса в г. Хабаровске, 1949 год. Оценка значения нравственной неотвратимости наказания для защиты будущих поколений.

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METHODOLOGY

The methodology is based on a detailed ethical commentary of two phenomena related to the history of biomedical research in Russia. The first is represented by the article by B. V. Dmitriev (B. V. D.) entitled *'A Case of Thyroid Transplantation and Legal Issues Associated with Transplantations of This Kind'* first published in Tsarist Russia in [1]. (Attachment). The second concerns a global historical event associated with the trial against former Japanese soldiers held by the Military Tribunal of the USSR in the city of Khabarovsk in 1949. They were accused of manufacturing and using bacteriological weapons and convicted based on the legislation of the USSR (art. 1 of the Decree of the Presidium of the Supreme Soviet of the Union of the Soviet Socialist Republic dated April 19, 1943) [2, 3].

The historical perspective and scope of the selected facts are obviously ambiguous. However, they have something in common. It's an absolute involvement in comprehension and interpretation of in-depth truth about the epoch-making events accepted by the international society as a beginning of the new era in the history of biomedical research presented by the Nurnberg Code (NC) of 1948 [4]. Our comparative analysis covering a regulatory and social field with different time and scope but having a common ethical resonance of '*crimes against humanity'* during the Second World War and '*ethical medical agony*' of COVID-19 pandemic is based on the conceptual link [5, 6].

It is important that readers examine the content of this article in due sequence. Initial familiarization with the documents presented in the attachment and respective references argues in favor of the topic considered.

RESULTS AND DISCUSSION

Commentary 1

As mentioned above, our attention was initially directed to the article published by B. V. Dmitriev and entitled *'A Case of Thyroid Transplantation and Legal Issues Associated with Transplantations of This Kind'*, 1917 [1]. According to an opinion given in a number of messages previously reported by some authors, the '*receipt'* of a patient presented in the article can be considered as the first sample of a voluntary informed consent (IC) form, and may be not just in Russia [7–9]. The opinion is also important because the review of the recommended handbooks of bioethics in our country contains no reference to such a unique event. In our opinion, this shifts the historical time of an IC formation and its geographical distribution [10–13]. It is widely accepted that data on appearance of the concept of patient rights in world's medicine are controversial. The logics of how the events developed in Russia is unreasonably disadvantaged and limited, even in the works devoted to the topic. Thus, it is announced that '*the necessity of obtaining a patient's consent to a certain treatment regimen was not discussed even in special literature*' or '*in Russia, law-making processes regulating the rights of citizens while obtaining medical assistance were initiated only after the October Revolution of 1917'*; or that '*the issue of patients' right to information and taking a decision on their treatment was first considered in the USA and Western European countries, but not in Russia*' [14, 15]. Thus, it can be asserted that the issue of priority and regulatory status of patients' informing in Russia lies deep and requests principal inclusion into academic heritage, whereof it was justifiably declared in the process of ethical, cultural, philosophical and medical aspects of the issue' [16]. From this perspective, it is possible to reconsider the history of an IC in Russian research practice and shift the traditional idea of implementation of the IC ethical instrument in our country only from the moment when Russia joined the international acts (the Nuremberg Code, 1948, and the Declaration of Helsinki, 1964) to the launching position of domestic ethical and legal regulation in the early XX century (1917) [1, 4, 17]. Herein lies the historical value of the entire publication, and in particular the receipt of patient '*E.P.*' from the article by B. V. Dmitriev, which demonstrate a conjunction of the document with the acting standard of ethically acceptable modern IC elements [1]. We previously analyzed the original text of the mentioned '*receipt*' in detail and line by line compared with a list of requirements and positions set in the accepted ethical canon of biomedical research integrity, i.e., the Declaration of Helsinki [7].

In this article, we can once again confirm the qualitative ethical completeness of the century-old document constituents and their correspondence to the main acts such as the NC and DH in a responsible way without qualifying for matching the moral vigor of effect and authority. It is enough to start the comparison from the determinant thesis of the Nuremberg Code and its main principle which are as follows: '*Those who support human experimentation justify their views stating that the experimentation results are extremely useful for the entire society and can't be achieved using other methods of research. However, we all agree that certain fundamental principles which conform to the moral, ethics and law must be followed'*. According to the first provision of the NC, '*…the voluntary consent of the human subject is absolutely essential for a human experiment'* (NC, 1948) [4].

In the article by B. V. Dmitriev, we come across similar thoughts: '*Is a doctor entitled to do at least negligible and temporary harm to one healthy person for the benefit of the other?*' B. V. Dmitriev further expands the borders of responsibility which coincides with par. 4 and 5 of the Nuremberg Code describing a doctor's rights as follows: '*Is he competent to decide in every particular case whether benefit for one can compensate harm to the other when harm and benefit are considered in a broad sense, i.e., not just in relation to bodily health of these individuals but also taking into account an integrity of emotions and bodily forces of the both?*'. The author's response is totally concordant with the NC, as he states that the decisive factor for a doctor's decision is '*… law and human consciousness*'. The first lines of the 'receipt' taken from the article by V. B. Dmitriev are compliant with the fundamental NC condition on voluntary participation in the research: '*I, the undersigned E.K., willingly and with no outside influence… offered for transplantation …*' [1].

In the '*receipt by E. K.*' and the entire article by B. V. Dmitriev, we come across specific issues which are relevant not only to the Nuremberg Code, but also to the modern international and national standard of biomedical research, protocol of ethical, social and scientific requirements. The issues include research justification based on scientific data and medical indications, respect for individual autonomy, risk awareness and liability for data completeness and objectivity, compliance with freedom and voluntary choice, confidentiality, taking into account social and mental maturity of a clinical trial participant [1, 18, 19].

B. V. Dmitriev's thoughts about the legal aspect of a patient's informed consent, its accessibility and objectivity, compensation for voluntary participation and proving the lack of interest, conflict of interests and doctors acting independently are of special integrity. In particular, it is stated as follows: '*A doctor must explain to the donor (volunteer/ donor — explanation provided by the author — O. I. K.) every potential incident and danger of the future operation and obtain the donor's consent subsequently. To avoid any possible future complaints, it is better to provide the explanation and consent in writing in the presence of and signed by witnesses*' [1].

The mandatory condition of validity is a legally arranged agreement between a donor and a receiver which excludes the possibility of participation of '*the minor, weak-minded or those artificially excited'*; '*moreover, it is stated that the decision on participation must not result from 'mental constraint, deception, seducement, profit or authoritative advice'*, i.e., it must be voluntary and informed. The entire legal concept of informed participation in medical research, described in the article analyzed, lies on the acting regulatory basis interpreted by A. F. Koni, a highly-respected lawyer of Tsarist Russia in the beginning of the XX century. A. F. Koni mentions a lack of legally punished criminal activity associated with a sale of organs in therapeutic purposes, provides for a legal recommendation and evaluates the necessity to terminate trials [1]. The latter is an essential condition reflected in point 10 of the Nurnberg Code: '*During an experiment, a responsible investigator must be ready for its termination at any stage if professional considerations, good faith and cautious judgements… make it think that continuation of the experiment may result in an injury, disability or death of the one examined'* [4].

There is no doubt that it is possible to match conceptual characteristics of all messages from the analyzed article with monumental and acting documents developed in the XX and XXI centuries in a clear and deliberate way. However, the task of the present comparative analysis doesn't mean to define the superiority and equality, as the practice of patients' information was obviously present in the medical environment of various countries of the last century, though its hierarchy wasn't our interest. The primary objective of this part of the article has two constituents. First, one more page in national and world's history of bioethics is turned. It determines a just relation to the rich ethical heritage and potential of Russia in the area of bioethics, making the knowledge accessible for education.

Second, it is stated in a clear and persuasive way that no pseudo-justifying factors exist by the moment of barbarian and antihuman '*death experiment'* in the ideology of a state crime against the humanity during the Second World War. The factors include a lack of knowledge, standards/practice/conditions of ethical requirements for the research process.

The truth gives the result and conclusions of our first ethical commentary a global and civilized meaning. Intentional violation of all universal moral, professional regulatory norms and those available at the moment of crime commitment, deepens the abyss of guilt, inevitability of punishment and approaches the moral force of effect produced by the Nurnberg Code to the manifest '*on behalf of the insulted humanity consciousness'* [4, 5].

Commentary 2

Unlike the subject of our first ethical commentary, the events associated with the Military Tribunal of the USSR and legal trial against former Japanese soldiers accused of manufacturing and using bacteriological weapons in the city of Khabarovsk (1949) had a unique destiny. Due to political and ideological reasons, the Khabarovsk trial was initially almost in the wilderness or definitely in the shadow of the Nurnberg trial against Nazi doctors who performed sadistic medical human experiments. In the subsequent years, the Khabarovsk trial revealed to the world terrible archives of unhuman experiments on prisoners of unit 731 of Nazi Japan [2, 3, 20, 21]. Materials and facts from the publications and movies above show us a frightful record of a '*Japanese apocalypse'*. It was all left in the past. 70 years have passed since the Khabarovsk trial in 1949 and the world is dealing with a virologic disaster again. Thus, the article faces a specific task which is to discuss the ethical part of experiments over people perpetrated by Nazi Japan and their threatening echo heard during the COVID-19 pandemic.

B. G. Yudin, a Russian brilliant scientist in bioethics, devoted a deep philosophical and historical research to the issue of understanding an ethical constituent of the Khabarovsk trial [22]. In his article, B. G. Yudin states as follows: '*…the entire history of mankind puts at not so many cruelties compared with the 'trials' held not far from Harbin*'. Sheer cynicism of Nazi philosophy was revealed with an inevitable clarity, reducing to a minimum the effect of moral restraints on researchers, trial sponsors and potential users of the '*death laboratory'* results.

In his analytics, B. G. Yudin tries to answer the following question: '*How was is possible to conduct the sadistic experiments from the ethical point of view?*' [22].

We are using the ethical commentary to realize *why it was possible to forget the lessons taught by the sadistic experiments from the ethical point of view*. Unfortunately, the answer can be found in those events, which occurred soon after the Second World War. They accepted the compatibility of '*a genius and an evil-doer'* and justified the acceptability of using the results of the '*evil deed of genius'*. It is enough to look back at the fate of Shirō Ishii. He was the main '*scientific demon'* of 'unit 731'. He was given not just immunity to legal prosecution and ethical redemption, but also political patronage to continue bacteriological weapon trials in the leading centers of the USA [2, 3, 21]. Today, bioterrorism geopolitics covers all countries of the world and definitely exists in reality, originating from non-punishability/misprison of crime in Nazi Japan in spite of international limitation and prohibition law instruments [23].

The humanitarian, legal, social, economic and ecological crisis of COVID-19 pandemic demonstrates the destiny of a human civilization in the uncontrolled and inevitable reflection of a bacteriological/virological catastrophe, even in case of its natural development. Not to miss another lesson of global bioethics, it is necessary to refer to the humanitarian agenda of UNESCO, one of the most respected international structures in this sphere. By implementing the entire intellectual resource, experience and authority in drafting ethical recommendations on the most delicate issues of scientific ethics, UNESCO determined the strategy of actions in relation to COVID-19 as '*Protection of health and human dignity while respecting universal values'* [24].

Adherence to universal ethical principles and sequence of steps related to the ethical concept achievement and observance revealed a format and results of joint statements made by the leading structures of UNESCO in the area of bioethics such as the International Bioethics Committee (IBC), Intergovernmental Bioethics Committee (IGBC) and the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST). An opinion about a special significance of issues to struggle the pandemic was expressed during the first joint meeting in the headquarters of UNESCO in Paris on April 6, 2020. The topic was as follows: '*Ethical aspects to be considered during the global struggle with COVID-19 pandemic*'. They include *'exacerbation of mental stress among vulnerable and marginalized individuals and groups; collective recognition of growing vulnerability factors to produce response measures in healthcare and social politics in the world; interdependence of states providing the accessibility of protection measures, development of politics in public healthcare and stimulation of research: international cooperation in view of solidarity and responsibility of rich countries providing help to poor countries'* [24].

Even a cursory look at the list and concerns of UNESCO suggests a dramatic unacceptability of injustice and moral use of some people for the assumed benefit of others. This is the lesson provided by the Nurnberg and Khabarovsk trials. Audrey Azoulay, Director-General of UNESCO, makes the ethical appeal obvious stating that '*this crisis encourages the best traits of humanity with ethical principles serving as a compass*' [24]. She also mentions here that political decisions must be based on scientific knowledge and follow ethical standards. An important point is that UNESCO lays the entire responsibility for rational ethics on itself and national bioethics committees.

Social and ethical maturity of the strategy is undoubtful. However, these principles are not continuously followed everywhere and always. The author's attempt to carry out an ethical monitoring of the pandemic resulted in a '*sad truth*' of disturbed autonomy, discrimination, dysbalanced justice, cascade disturbances of medical aid accessibility and development of humanitarian disasters [25].

The most vivid contradiction between ethical solidarity and adequate conclusion made from the lessons of the past was '*vaccine egocentrism'*. This looks especially bad under the conditions of a panhuman disaster and panhuman dependence to leave the pandemic. UNESCO reacted to the moral crisis with the second joint announcement of IBC, IGBC and COMEST treating COVID-19 vaccines as a global common good (Paris, February 24, 2021) [26].

To understand the scope of ethical anti-solidarity, it is enough to provide some principal ideas the announcement is based on. '*When vaccination campaigns were announced worldwide, everyone was relieved. We are far from the goal achievement without solidarity, as over 130 countries failed to get a vaccine yet, and the most vulnerable layers of population are still not protected'* (Audrey Azoulay, Director-General of UNESCO) [26].

'We won't come over the pandemic wherever it takes until it is over everywhere. In the end, the justice of vaccination is not just a correct choice but the best way to control the pandemic, restore trust and reactivate world economy…' (D-r Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization).

CONCLUSION

The basic and enlightening conclusion for the activity designed to formulate ethical commentaries to two events of various scope but with the same moral force of effect should be an absolute and indisputable moral association of human decisions and deeds of the present, past and future. The axiom requires responsible thoughts about the heritage prepared by the current generation of scientists and doctors for their descendants. Humanistic wealth of mankind formulated by V. R. Potter should be considered as a standard in bioethics determination: '… A science of survival must be more than science alone, *it must be the new wisdom, which could unite two most important and essential ingredients such as bacteriological knowledge and universal human values*' [27].

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Attachment

EXTRACTS FROM THE ARTICLE BY DMITRIEV BV *'A CASE OF THYROID TRANSPLANTATION AND LEGAL ISSUES ASSOCIATED WITH TRANSPLANTATIONS OF THIS KIND'. MEDIZINSKOYE OBOZRENIYE*, 1917; LXXXVII (13–16): 618–619, 626–628 P. RUSSIAN.

SURGERY. A CASE OF THYROID TRANSPLANTATION AND LEGAL ISSUES ASSOCIATED WITH TRANSPLANTATIONS OF THIS KIND

Written by Dmitriev BD, Chief Physician of the Machinery Plant in Kolomna

In December 1909, a student NN, 26 y.o., presented with complaints of severe forms of hypothyroidism and asked for thyroid transplantation.

'In 1907, she read that Prof. Christiani from Geneva successfully treated cretinism with thyroid transplantation. She went there at once, and Christiani transplanted freshly cut pieces of goiter under her skin (at eight sites). According to NN, the surgical outcomes were very good. There was no need to take thyroidin for almost a year. She felt especially well during the first month after the injection. However, by the end of the year she began taking thyroidin again due to a worsened well-being. She was in Paris that time. In summer 1908, she requested transplantation from Walther. Walther injected thyroidal parts taken from a healthy man under her skin (at seven sites). This made her feel satisfactory for about three months only. Christiani assured that the second operation was not successful due to an insufficient implant amount and advised to repeat the transplantation using a healthy gland. For this purpose, NN referred to me in the end of 1909 stating that her maidservant was ready to sacrifice her gland for 50 rubles (!)

The right of a doctor for human-to-human transplantation of tissues and organs is of a keen interest from the legal point of view. Does a doctor have a right for harming a healthy person for the benefit of someone else, even if the harm is insignificant and transitory? Is he competent enough to decide whether benefit of one person can compensate for harm to the other one? Benefit and harm are comprehended in the broadest sense here: not only as the physical health, but also as an entity of physical and mental health of the individuals. During the practice, a doctor will have to come across similar issues, and their resolution is not that simple. For instance,

producing a miscarriage, embryotomy, selection of wet nurses. Law and consciousness place a high value on a human life, even at the embryonal level, and allow to destroy it only when there is an evident risk for a maternal health. As far as the embryotomy goes, a maternal life is obviously more valuable than the life of a mature fetus. However, a doctor often places a mother at risk to preserve the fetus. These provisions can be considered as generally accepted — though with some exceptions. Unfortunately, neither society, not doctors have one opinion about wet-nursing. Wet nurses usually deprive their own children of breast feeding in favor of formula feeding, exposing them to all related dangers.

The client requests a doctor just to estimate a wet nurse's health and her milk quality, sanctioning the deal. Meanwhile, a child is entitled to breastfeeding, not capable to maintain his own rights and demands protection. The doctor who examines the wet nurse's health must protect the child. A doctor performing transplantation occupies a similar position. The analogy is more perfect when a donor donates a body part in return for a fee and becomes absolutely perfect when the donor is a minor, insane or of little culture. In the first case, the doctor should use the strength of words and persuade the mother not to deprive her own child of milk; in the second case, the doctor must refuse from using body parts of minors and those insane for the purpose of transplantation. Specimen of homologous grafts can be taken from a responsible adult only. It is necessary that the harm provided by a body part removal be transient and based on precise scientific data. The doctor must provide for an exhaustive explanation of all possible accidents and dangers of the coming surgery and make the patient explain the consent provided. To avoid possible problems in the future, the explanation and consent must be given in writing in the presence of and under the signature of witnesses.

What should a doctor do, when a person donates a body part at a charge? It seems to me that a doctor must not act as a mediator or advisor for the financial part of the agreement; there is absolutely no way he should link an amount of a transplanted organ to the money paid.

I have already mentioned that my patient paid 50 rubles for the gland. The amount was offered by the donor. Though I found out later in the context of skin transplantation that the donor had already been paid for the skin provided, I should acknowledge that the sales procedure seemed confusing to me. Explaining the consequences of the action to the donor and entering the record I didn't mention the financial part of the deal following the advice of a Moscow lawyer'.

Let me cite the full text of the document: 'I, the undersigned EP, offered a part of my thyroid gland with the size necessary for successful transplantation (approximately, one eighth part hereof) without any irrelevant influence. I was explained in detail and I understand well all the possible related dangers. Thus, an unsuccessful surgery may result in a life-threatening bleeding, neck suppuration or even sepsis that may be fatal. I was explained that the effect of the future surgery on a human health was not known yet, as the surgery was rarely performed, and experience of those people who underwent the surgery was not reported. However, it is proved that removal of two thirds of the thyroid in animals won't do any harm. So, the conclusions can be applied to humans as well, as the glands of animals and people have much in common. It is enough to leave a small portion of the thyroid in a person with a thyroid tumor and the person will continue living without suffering from the gland deficiency. I am aware of the consequences that occur in case of gland deficiency. I was also explained that in spite of anesthetics given I will still feel some pain during and after the surgery. I was also told that in case of success or suppuration, I would get a scar on my neck that would be 2.6–3.5 inches long. Notwithstanding the above, I still agree to have the surgery. I shall under no circumstances hold a demand against the doctors performing the surgery and the patient who needs the transplantation. I am signing the paper in the presence of doctors Dmitrieva BV, Vinokurova EK, Alekseeva MP and nurse Schevchenko EV (signature). We witnessed the reading and signing of the paper and certify that E.P. is an adult and mentally healthy person' (signatures of the doctors and nurse).