ETHICAL ASPECTS OF THE INFORMED CONSENT DURING COVID-19 VACCINATION

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The main tactics used for COVID-19 prevention should be both quarantine measures and the large-scale vaccination of the population. This does raise many ethical issues related to obtaining informed consent in biomedical research and clinical practice. The full and adequate ethical review of vaccination against the novel coronavirus infection can be provided only subject to ethical aspects of voluntary informed consent. Without that, it would be impossible to control the quality, efficiency and safety of the vaccine, and, consequently, the patients' vaccination and its results.

Keywords: healthcare, medicine, biomedical ethics, voluntary informed consent, COVID-19.

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ЭТИЧЕСКИЕ АСПЕКТЫ ДОБРОВОЛЬНОГО ИНФОРМИРОВАННОГО СОГЛАСИЯ ПРИ ВАКЦИНАЦИИ ПРОТИВ COVID-19

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Основной тактикой профилактики COVID-19 должны быть не только карантинные мероприятия, но и масштабная вакцинация населения. Поэтому возникает множество этических вопросов, связанных с получением добровольного информированного согласия в биомедицинских исследованиях и клинической практике. Этическую экспертизу вакцинации против новой коронавирусной инфекции можно провести полноценно и адекватно лишь при условии соблюдения этических аспектов добровольного информированного согласия. Без этого нельзя проконтролировать качество, эффективность и безопасность вакцины, а, следовательно, вакцинации пациентов и ее результаты.

Ключевые слова: здравоохранение, медицина, биомедицинская этика, добровольное информированное согласие, COVID-19.

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Introduction

In March 2020 the WHO reported on the new global pandemic of COVID-19 [1]. To date, the pandemic has affected most countries in the world and almost all constituent entities of the Russian Federation. In addition to restrictions on freedom of movement, quarantine measures cause considerable economic damage, especially to small and medium-sized enterprises, and result in economic downturn and rising unemployment [2, 3]. People fall out of the real economy in some way due to self-isolation. The basket of goods is changing, and there is a growing demand for personal protective equipment and hygiene items. The costs to the health system are increasing [4]. The decline in tourism, transport industry, and entertainment industry is evident. In some instances, social stress and psychological discomfort are responsible for people's failure to comply with the quarantine regime [5]. Some people easily fall into panic [6].

That is why the main tactics used for prevention of the novel coronavirus infection should be both quarantine measures and the large-scale vaccination of the population. However, people experience difficulties with navigation in the flow of information, as well as with selection of reliable information, including information on developing, testing, and applying the vaccines. This does raise many ethical issues related to obtaining informed consent in biomedical research and clinical practice.

RESULTS AND DISCUSSION

The legislative framework for the ethical reviews during development, testing, and using the vaccines, is provided for by the Constitution of the Russian Federation (passed by popular vote on December 12, 1993, with modifications adopted in the course of all-Russia voting on July 1, 2020). Part 3 of the Article 55 stipulates:

"1. The listing in the Constitution of the Russian Federation of the fundamental rights and freedoms shall not be interpreted as a rejection or derogation of other universally recognized human rights and freedoms.

2. In the Russian Federation no laws shall be adopted cancelling or derogating human rights and freedoms.

3. The rights and freedoms of man and citizen may be limited by federal law only to the extent necessary for the protection of the fundamental principles of the constitutional system, morality, health, the rights and lawful interests of other people, for ensuring defence of the country and security of the State" [7].

The legislative framework for ethical reviews of vaccine testing and use in the Russian Federation is also regulated by federal laws and regulations, as well as by the orders of the Government and the Ministry of Health, and by recommendations of Rospotrebnadzor.

From an ethical point of view, preventive vaccination usually entails the need to resolve the conflict of interest. It is known

that during the development and testing of new vaccines, the two matters, often contradictory, are to be resolved:

1) obtaining credible evidence of the vaccine efficiency and safety;

2) protecting health and lives of the clinical trial participants.

Currently, the ethical aspects of the vaccines against the novel coronavirus infection clinical trials are under active discussion both in Russia and worldwide. Getting comprehensive and reliable scientific information about such vaccine efficiency and safety goes hand-in-hand with the need for adherence to fundamental ethical principles and standardization of ethical reviewing of vaccine clinical trials. This is a mandatory requirement for the new drug registration and manufacturing.

There are some additional risk factors, which make this process more difficult. Vaccination can potentially involve much of the world's population (up 70% of the population), which, in fact, gives the researchers no room for error. There is also some fair criticism, and founded complaint from vaccine refusers. It is an impermissible miscalculation to ignore their vision.

Mandatory compulsory vaccination is a crucial social and political issue that affects public life, economy, and finances of all countries. Furthermore, safety standards and ethical review issues, set out during the vaccine clinical trials, are usually more complex than those set out during investigation of other medications. These features underlie the multi-layered nature of the conflict of interest, and require development of the legal and ethical framework, as well as appropriate training of members and experts of the Ethics Committees of different countries.

The first international instrument, outlining the ethical principles of clinical trials involving human subjects, is the Belmont Report, introduced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [8]. The report identifies three basic ethical principles:

• The principle of respect for persons calls for voluntary participation in the vaccine testing. To this end, potential participants or their legal representatives should be provided all the necessary information about the trial, and should make an informed decision. The researchers shall obtain the participants' written consent prior to experiment.

• The principle of beneficence implies two rules: do not harm, maximize possible benefits and minimize possible harms. Hence the need for assessing the balance between benefits and risks. In certain cases, participation in the clinical experiments can contribute to the increased risk of the disorder in the future or produce the immune response not strong enough.

• The principle of justice (fairness in distribution): the benefits and burdens of research participation should be fairly distributed among all groups involved, irrespective of age, gender, location, ethnic or racial background, etc. The potentially vulnerable groups of experimental subjects are identified, for example, individuals fostering an excessive sensitivity to the harmful effects (pregnant women, elderly people, disabled persons), individuals incapable of giving informed consent (children, mentally disabled people), and individuals, whose informed consent could be called into question (military personnel, migrants, prisoners).

The Council for International Organizations of Medical Sciences, together with the World Health Organization, defines the concept of vulnerability as the relative (or absolute) incapability of protecting the person's own interests. Vulnerable groups are those having an increased likelihood of being wronged or of incurring additional harm, often abused by those who have a capacity to harm [9].

The informed consent given on a voluntary basis is a basic guarantee of the rights, and respect for the dignity of any biomedical research participant. In order to maintain the benefit-risk balance, the information provided should include the description of all benefits and risks related to research participation, alternative protection methods, medical and social consequences of participation and refusal to participate, insurance and state guarantees, etc. The essential principle of the new vaccine trial ethical review is protecting the confidentiality of participants' information and experimental results.

In fact, the informed consent is an informed decision concerning the proposed treatment option made by competent patient on a voluntary basis based on the full, objective and comprehensive information about the forthcoming treatment, possible complications and alternative treatment options [10, 11].

This process stresses the ethical value of the patient's participation and personal autonomy. It is necessary to explain the interventions of certain protocol to potential participant, teach him about his rights as a clinical trial participant, explain the essence of the studied scientific question, the experimental method, as well as the trial potential benefits and risks. The procedure must be thoroughly recorded [12, 13].

The Ministry of Health of the Russian Federation (the letter dated December 9, 2020, № 17-о/и/2-18965, and the letter dated January 15, 2021, № 1/И/1-155) has issued the Standard Operating Procedure "The procedure for COVID-19 vaccination in adults" [14, 15]. The first officially registered Gam-COVID-Vac vaccine is to be used, the combined vector vaccine for prevention of coronavirus infection caused by SARS-CoV-2.

Annex № 5 is referred to as "Informed consent to vaccination or refusal of vaccination" [16]. Having signed that document, the patient demonstrates that the physician has informed his/her about the following:

1) preventive vaccination involves administration of immunobiological medicinal product in order to generate the specific unresponsiveness to novel coronavirus infection (COVID-19) in adults. The vaccine employs biotechnological methods, which do not use the SARS-CoV-2 virus pathogenic for humans. The medicinal product consists of two components;

2) the need to perform preventive vaccination in two phases and contraindications to vaccination;

3) possible post-vaccination reactions: systemic (short-term flu-like syndrome, characterized by fever, arthralgia, myalgia, asthenia, general feeling of malaise, headache), and local (soreness around the injection site, hyperemia, swelling), which can occur during days 1–2 after vaccination and resolve during the next three days;

4) compulsory medical examination before each stage of vaccination (medical survey if required);

5) compliance with the prescriptions of medical professionals.

Then, the document declares, that the patient was provided an opportunity to ask any question and received a full reply, which was properly understood. That is indicative of the informed consent to vaccination (in this case, using Gam-COVID-Vac, the combined vector vaccine for prevention of coronavirus infection caused by SARS-CoV-2).

CONCLUSION

Ethical review of vaccination against the novel coronavirus infection entails improving preventive immunization and general achievements of scientific and technological progress. Such full and adequate ethical review can be provided only subject to ethical aspects of voluntary informed consent. Without that, it would be impossible to control the quality, efficiency and safety of the vaccine, and, consequently, the patients' vaccination and its results.

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