

## CLINICAL TRIALS OF COVID-19 VACCINES AND VACCINATION CAMPAIGN: ETHICAL ISSUES

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For many centuries, infectious diseases have posed a serious threat: epidemics and pandemics claim lives and multiply the burden on health systems and countries' economies. Humanity managed to defeat a number of infections only thanks to specific preventive measures, i.e., vaccination. In 2020, society faced the new COVID-19 virus that has swept the whole world. The situation required swift and decisive action, including in what concerned vaccine development. It has also raised a number of ethical issues. The article analyzes ethical issues related to clinical trials and vaccination against COVID-19 by studying the regulations, literary sources and bioethical incidents. The key problems identified are: human participation in clinical trials during a pandemic, availability and, simultaneously, voluntariness of vaccination, public confidence in the SARS-Cov-2 vaccines approved for clinical practice. The study showed that the basic principles of clinical trials, voluntariness and awareness, are violated. It was revealed that despite all the efforts of public organizations and WHO initiatives in the world, there is a pronounced imbalance in the availability of the developed vaccines, while the vaccination voluntariness principle is violated by application of various mechanisms to put pressure on people, and public confidence in the developed vaccines can be called insufficient. In general, the problem of vaccination against COVID-19 remains relevant and requires comprehensive discussion.

**Keywords:** COVID-19 vaccination, clinical trials of vaccines, voluntary vaccination, COVID-19 vaccine availability, SARS-Cov-2 specific prevention

**Acknowledgments:** author would like to thank Tatyana Aleksandrovna Sidorova, Associate Professor of the Department of Fundamental Medicine of Novosibirsk State University, for criticizing author's ideas, text editing and extensive assistance in preparing the article.

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**Received:** 12.04.2021 **Accepted:** 24.05.2021 **Published online:** 25.06.2021

**DOI:** 10.24075/medet.2021.016

## ЭТИЧЕСКИЕ ВОПРОСЫ ПРОВЕДЕНИЯ КЛИНИЧЕСКИХ ИССЛЕДОВАНИЙ И ВАКЦИНАЦИИ ПРОТИВ COVID-19

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Инфекционные заболевания на протяжении многих столетий представляли серьезную угрозу: эпидемии и пандемии уносят жизни, многократно повышают нагрузку на системы здравоохранения и экономики стран. Человечество смогло победить ряд инфекций только благодаря мерам специфической профилактики — вакцинации. В 2020 году общество столкнулось с новым вирусом COVID-19, охватившем весь мир. Ситуация требовала быстрых и решительных действий, в том числе и в аспекте разработки вакцин и породила ряд этических проблем. В статье проанализированы этические вопросы, связанные с проведением клинических исследований и вакцинации против COVID-19. Основой выступили нормативные правовые акты, литературные источники и биоэтические казусы. Обозначены ключевые проблемы: участие человека в клиническом исследовании в условиях пандемии, доступность и одновременно добровольность вакцинации, доверие общества к допущенным к клинической практике вакцинам от SARS-Cov-2. Проведенное исследование продемонстрировало, что имеет место нарушение базовых принципов проведения клинических исследований: добровольности и информированности. Выявлено, что, несмотря на все усилия общественных организаций и инициативы ВОЗ, в мире имеется выраженный дисбаланс в доступности разработанных вакцин, одновременно с этим, отмечено нарушение добровольности вакцинации и факт использования различных механизмов давления на человека, в то время как доверие общества к разработанным вакцинам можно назвать недостаточным. В целом проблема вакцинации COVID-19 остается актуальной и требует всестороннего обсуждения.

**Ключевые слова:** вакцинация COVID-19, клинические исследования вакцин, добровольность вакцинации, доступность вакцины COVID-19, специфическая профилактика SARS-Cov-2

**Благодарности:** доценту кафедры фундаментальной медицины Новосибирского государственного университета Татьяне Александровне Сидоровой за критику авторских идей, редактирование текста и всестороннюю помощь в подготовке статьи.

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**Поступила:** 12.04.2021 **Статья принята к печати:** 24.05.2021 **Опубликована онлайн:** 30.06.2021

**DOI:** 10.24075/medet.2021.016

COVID-19 pandemic continues its march across the planet. The current challenge is to find effective, safe and affordable ways of specific prevention, which keeps the problem of developing and conducting clinical trials (CT) of COVID-19 vaccines urgent.

From the ethical perspective, organization of human clinical trials is a multifaceted matter: there are rights of the patient-participants, guarantees of their safety, limits of responsibility of the researchers, control of quality of the activities carried

out. The current pandemic makes everything even more complicated because the trials need to be conducted in difficult epidemiological conditions.

The problem of availability of the vaccines allowed on the pharmacological market is equally important. WHO has suggested a number of initiatives as solutions thereto: COVAX (ensuring equitable access to COVID-19 vaccines), 100 days (ensuring vaccination of all health care workers and the elderly at greatest

risk, worldwide, within the first 100 days of the year), Declaration on Equitable Global Access to COVID-19 Vaccines [1].

This study aimed to analyze ethical issues arising in connection with clinical trials and COVID-19 vaccination campaign.

Currently, the researchers pay greatest attention to the issues of the voluntariness principle observance and protection of the patients' rights in the context of both CTs and the mass vaccination. There is also a number of articles covering ethical issues of vaccine development in the current pandemic. Some authors considered the possibility of infecting a human being with SARS-Cov-2 deliberately, for a research purpose of assessing the effectiveness of vaccination, substantiating the benefits this approach offers society (reliable data, new information, accelerated development of an effective vaccine), emphasizing ethical issues (high health risks the volunteers are exposed to, uncertainty about the consequences of the infection), highlighting the fact that a pandemic is a significant threat to society and, under such conditions, the risk can be justified [2]. Other researchers focused on the safety of the developed vaccines both for volunteers and those who will be vaccinated later during the mass vaccination campaign, highlighting such problems as the reduced duration of the first phase of studies, decision to forego animal testing made by some companies, launch of CTs without convincing data on the safety of the drug. Most authors arrive at the conclusion stating the importance of strict adherence to all ethical requirements for conducting a clinical trial, protecting the rights and safety of the volunteers, especially vulnerable groups [3]. In any case, the need for a vaccine CT in the pandemic era only exacerbates unresolved ethical issues and introduces new ones that require discussion.

As for the equity of access to vaccines, the commonly discussed issues are those of vaccination of the most vulnerable groups of the population, vaccines distribution criteria, availability of the vaccines to countries of the world and their capability to buy them [4]. The religious and legal aspects of the vaccination are also analyzed [5].

## STUDY RESULTS AND DISCUSSION

### Ethical considerations concerning clinical trials of the COVID-19 vaccines

Human trials have been practiced in medicine since the 18th century [6], but it was not until the middle of the 20th century that the documents regulating them were developed, stating rights of the patients and obligations of the researcher, as well as touching upon ethical issues [7]. Everyone is well aware of the horrific experiments carried out by medical workers in Nazi Germany on the concentration camp prisoners [8], as well as what was done by Unit 731 of the Japanese armed forces [9] and a number of other researchers whose studies involved human participation. The first document that outlined the rules for conducting studies was the Nuremberg Code of 1947 [10]. Later, in 1964, there appeared the Declaration of Helsinki, which was subsequently revised seven times, with the current revision being that of 2013. The Declaration was developed by the World Medical Association; it is a set of ethical principles developed for the medical community and governing research with involvement of people. The Declaration expands the provisions outlined in the Nuremberg Code and updates them. The Principles of Good Clinical Practice, which were adopted in 1974, are the standard document regulating CTs today, with no experimental protocol organized and implemented without observance thereof [11]. The Principles form the basis of the Russian Federation Research Execution Standard. The above documents underscore the importance and role of the informed

voluntary consent given by the research subjects, the need for a permission from the Ethics Committee, for consideration of the specific interests of vulnerable categories of patients, observance of the ethical principles of confidentiality, as well as balance of benefits and risks for the subjects, fairness, etc.

In the context of the COVID-19 pandemic, the principles discussed have not changed. Despite the complexity of the situation with the spread of the new coronavirus infection, the requirements organizing and conducting CT must be strictly observed and conform to all international standards. In the Russian Federation, research activities are regulated by the Federal Law "On Circulation of Medicines" [12], the Russian Federation National Standard (GOST R 52379–2005 of 2005) and a number of explanatory letters from the Federal Service for Surveillance in Healthcare. The analysis of expert opinions about the possibility of making requirements for vaccine clinical trials less strict in order to accelerate development of the vaccines and have them introduced to the daily practice faster yielded a conclusion that vaccine safety is prioritized and health of volunteers participating in the vaccine tests is paid much attention to. In summer of 2020, A. L. Gintsburg, director of the Gamaleya Research Institute, pointed out that vaccine development cannot be compared to a run, research takes time and must be carried out at the highest level [13]. Along similar lines, European Medicines Agency has published an official statement to its website noting the need for exceptional transparency of the COVID-19 vaccine CTs [14].

The problem of public confidence in the results of tests comes to the fore, since this confidence greatly affects people's readiness to be vaccinated and their sense of security in the context of the current pandemic. The traditional issues of voluntary participation in the research, proper information campaigns for the patients, safety of their life and health also remain as relevant as they were.

### Ethical issues of COVID-19 vaccination

There is an official definition of preventive vaccinations in the Federal Law 157-FZ of September 17, 1998 "On Immunoprophylaxis of Infectious Diseases", which enshrines vaccination as introduction of immunobiological drugs into the human body with the aim to create specific immunity to infectious diseases. The same law enshrines the concept of the National Vaccination Calendar, which lists the preventive vaccination types, terms and procedures. Introduction of the National Vaccination Calendars, routinely revised and updated and adjusted to the epidemiological situation, enabled the human race to overcome many infectious diseases, reduce morbidity and mortality [15].

Vaccine safety became an investigated topic in the middle of the 20th century, but the first regulations making vaccine testing mandatory were not adopted until the 1990s, and WHO launched its Global Vaccine Safety Initiative only in 2012. These documents emphasize the importance of all stages of a study, point out lack of a legal way to leave out any of them, prescribe much attention to the protocols and results of the clinical stage, highlight the importance of vaccination as an effective method of prevention of the spread of infectious diseases [16].

The idea of how effective vaccines are in terms of prevention took shape in the 19th century, and the 20th century saw mass vaccination campaigns organized throughout the world, including the developing countries [17]. Currently, public vaccine hesitancy is gaining momentum: in 2019, WHO included lack of confidence in vaccination in the list of ten global threats to public health. The roots of the anti-vaccination movement date back to the 19th century, when, shortly after the development of the first smallpox vaccine, first anti-vaccination organizations

began to emerge. At the beginning, the protests were mostly religious in nature, but towards the end of the 19th century their focus was shifted to the vaccines' insufficient efficacy and safety and human rights violations when vaccination was declared mandatory [18]. Today, the anti-vaccination movement also focuses on the problem of safety of immunoprophylaxis drugs. According to a study conducted in 2012 jointly by scientists from the UK and Australia, over 20% of parents do not fully trust vaccine prevention campaigns [19], and in Russia, as of 2016, 28% of the public exhibited vaccine hesitancy [20]. The new coronavirus infection has exacerbated this problem significantly: the extraordinary need for a vaccine, the short time between CT launch and public release of the drug, fears about the compulsory nature of COVID-19 vaccination — all these factors may add to a person's decision to refuse vaccination.

On the other hand, when some countries struggle to motivate their citizens to get the COVID-19 vaccine shots, other states cannot afford purchasing them even for medical workers and the most vulnerable groups of their population. This is the problem that WHO is focusing on with COVAX, a mechanism developed as part of the initiative to accelerate access to the SARS-CoV-2 remedies [1], which is designed to enable cooperation in the interests of equitable access to COVID-19 vaccines throughout the world. COVAX aims to provide vaccine to at least 20% of the population, end the acute phase of the pandemic, restore the economies of the most severely affected countries. The first country to receive the vaccine through COVAX was Ghana (on February 24, 2021), and overall, there were over 38 million vaccine doses delivered to more than 100 countries worldwide.

Thus, the availability of the drug for all categories of the population and the voluntariness of both vaccination and participation in the CTs can be singled out as urgent ethical problems associated with vaccination against COVID-19. Officially, Russian Federation declares strict adherence to the principle of voluntariness, but the real situation has somewhat different features.

### **Cases of ethical violations in the context of CTs and the vaccination campaign**

Here are some examples of how CTs and mass vaccination are handled with the current COVID-19 pandemic in the background. On October 6, 2020, Elizabeth Focht, a BBC Russia journalist, published an article with a telling title of "Some learn where they came to only upon arrival: the who and the why of Russian coronavirus vaccine testing" [21]. The author conducted her own investigation and interviewed people who came to the volunteer center recruiting coronavirus vaccine CT participants in Moscow. One of the main goals of the investigation was to learn motivation of the volunteers. According to the survey, some of the respondents were sent by their employer to undergo a mandatory screening with the aim to subsequently enroll them in a CT. Also, as mentioned by the respondents, some experienced certain pressure from the employer, like threats of dismissal, bonus deprivation, "a promise of problems at work." Some were asked to "just check in" at the center to increase the footfall numbers. In this case, the key ethical problem is non-adherence to the principle of voluntariness in recruiting CT participants, which is a gross violation of the GCP principles that may add to the public distrust towards the results of such a CT. We believe that recruiting volunteers when there is a need to accelerate transition into the clinical phase of trials generates a serious ethical, legal and social problem that cannot be solved only with administrative measures and material incentives encouraging participation, which are simply a wrong tool in some cases.

Here is another case (from our own practice) related to the voluntariness of vaccination against COVID-19. A large company purchased a certain number of COVID-19 vaccine doses and offered its employees vaccination. Managers of the company's units received plans stating the required number of vaccinated employees, and the implementation of these plans was linked to the amount of bonus paid at the end of the quarter. The managers resorted to various measures aiming to influence their subordinates and to motivate them to get the vaccine shots. Some of the employees who did not want to be vaccinated had to either confront their immediate superiors or look for reasons to avoid immunization against COVID-19: contraindications, imitation of illness, pregnancy, etc. The analysis of this situation raises a number of questions. First, why has the company not attempted other ways to motivate its employees, e.g., campaigns to increase confidence in the vaccine, outreach events, meetings or conversations with a vaccine or infectious disease specialist? Secondly, can it be considered justified to force a person to vaccinate against his/her will, even for good purposes? Does this stance of the employer not violate the law, which establishes strict voluntariness of vaccination?

### **Sharing the burdens and the benefits: the challenge of vaccine availability**

According to WHO, developed countries show the largest coverage of the population with preventive vaccinations against the new coronavirus infection, while most developing countries cannot afford to purchase the vaccines. At the same time, experts emphasize the extraordinary importance the widest possible vaccination has in the matter of reducing the virus spread and mutation. Only a joint effort by the entire world community can ensure provision of the poorest countries with a safe and effective vaccine. A number of WHO initiatives discussed above and designed to solve this task, of course, requires further development and implementation, because cooperation is the only way to stop the pandemic, and access to what medicine has to offer must be equal and fair.

Besides, there is another fairness-related factor associated with SARS-CoV-2 vaccine CTs: the distribution of burdens and benefits. The so-called third world countries have traditionally been used by pharmaceutical companies as testing grounds for their new drugs, including vaccines, and the interests of the populations of those countries were not always taken into account. Currently, when the very participation in vaccine trials could be beneficial, third world is not the place to host CTs, which leaves the countries thereof without priority access to the vaccines [22].

### **Safety and efficacy of COVID-19 vaccination**

As indicated above, the main priorities in vaccination are the efficacy and safety of the drug for human beings. Preclinical and clinical studies serve to establish the former and the latter, and the results obtained form the basis for use of the drug in routine practice, factoring in contraindications and possible adverse events. A good example is the safety-related situation around the AstraZeneca COVID-19 vaccine: the registered adverse side effects thereof are thrombosis and thromboembolism, with death being the possible ultimate outcome. A series of studies enabled EMA to conclude that the benefits of vaccination outweigh its risks, and rare side effects are to be expected when vaccinating on the scale of millions. Nevertheless, some countries have withdrawn the approval for use of this vaccine [23]. This is when an ethical question arises: how justified is it to expose a healthy person to the risk of a severe outcome, minimal as it may be, in order

to specifically prevent COVID-19? What should be the relation between personal risks and interests of the public? Is it possible to maintain public confidence in vaccine-based prevention after publication of the results of such post-marketing research efforts? In our opinion, given the pandemic, the objective need for vaccination and the proven efficacy of the drug, it is necessary to study the complications that have occurred in more detail, identify the risk groups, develop preventive measures, provide patients with exhaustive information and give them the choice of taking the shot of the drug in question or refusing the vaccine.

More and more frequently, mass media voice questions about the EpiVacCorona vaccine developed at the State Research Center of Virology and Biotechnology VECTOR. For example, participants of the 3rd phase of the CT sent an open letter to the Ministry of Health of the Russian Federation, Roszdravnadzor (Federal Service for Surveillance in Healthcare) and VECTOR, stating lack of antibodies to SARS-Cov-2 in more than half of the volunteers, while earlier VECTOR has reported that all (100%) of participants had them [24]. At a meeting with the volunteers, VECTOR representatives pointed out the complex mechanisms behind vaccine-induced development of the immune response, noted that vaccination does not guarantee protection against infection but helps avoid severe course of the disease. Many questions also arise because of the lack of publications covering the CT results in peer-reviewed journals. To date, not a single peptide vaccine against the new coronavirus infection has been registered for practical use in the world, mainly due to insufficient immunogenicity, i.e., efficacy. The discrepancy between VECTOR's statements and the results that CT participants present as an efficacy descriptor raises public doubts about the effectiveness of the vaccine and the "transparency" of the trials. Of course, development of the SARS-CoV-2 vaccines is accompanied with a very large number of purely scientific questions revolving around the real efficacy of the protection mechanisms set up by the vaccine, and whether it is possible to eradicate the new plague of the 21st century relying on the traditionally used immunization methods. However, these situations, which imply vulnerability from the point of view of science and health, will be better resolved if the population is worked with competently and openly.

The issue of vaccination efficacy enormously important, especially in the current pandemic. To implement the principle of awareness in the context of the vaccination campaign, it is necessary to make the research results accessible, heard and read, as any lack of information and alarming messages in the media only exacerbate vaccine hesitancy. The limited choice of vaccines gives rise to an ethical problem: if a vaccine's efficacy was not confirmed by the generally accepted methods, how well-protected from the infection can a person that received this vaccine should feel himself/herself? In case of EpiVacCorona, this problem becomes even more important, since it is marketed as the safest vaccine for the vulnerable categories of citizens, i.e., the elderly and people with severe chronic diseases.

## CONCLUSIONS

Analysis of the literature, expert and public opinions yields a conclusion that the key ethical problems associated with the COVID-19 CTs and vaccination are compliance with the principles of awareness and voluntariness, patient safety, vaccine availability for the population, priority of vaccination, public confidence in the CT results. In our opinion, with the current pandemic in the background, it is very important to disclose the results of all the CTs and make their protocols transparent for experts and understandable by the public. At the same time, regardless of how complex the epidemiological situation is, it should be considered unacceptable to violate the GCP principles, neglect the ethical foundations of the CTs and disregard the principles of voluntariness and awareness of trial participants. As for the vaccination campaign, the matters of vaccine efficacy and safety should be prioritized, and the world community should tirelessly cooperate to ensure equitable access to the vaccines, thus helping stop the pandemic and normalize epidemiological situation in the world.

A comprehensive analysis of the cases considered allowed noting violations of the principles of voluntariness and awareness peculiar to both the CTs and the vaccination effort. Such messages could undermine public confidence in vaccination against the new coronavirus infection. The principle of voluntariness is a fundamental one in medicine, its violation is completely unacceptable; it is necessary to form a conscious attitude of citizens to the prevention campaign with vaccines and increase the level of awareness and trust of the population. The most effective way is to provide reliable information about benefits and risks, as well as the possible adverse events, thus enabling people to independently make the vaccination decision.

The analysis of statistical data describing current situation in the world showed that despite all the efforts of WHO and the initiative group, COVID-19 vaccines remain partly unavailable to poor countries, while the world community, nevertheless, continues with its effort to provide the most vulnerable population groups and medical personnel with the vaccines. Both national governments and pharmaceutical companies are joining the program, which allows hoping for a higher level of vaccine availability in the future and, consequently, decreased mortality and improved epidemiological situation. Also, despite the current CT requirements and WHO calling for their transparency and reliability, as well as compliance with the key principles, there are messages that challenge the basics: safety and efficacy of the vaccines. This state of affairs can aggravate public mistrust in vaccine-based prevention and requires additional attention from the governments, the expert community and the public.

In general, this work allows stating that the COVID-19 pandemic, the CT and vaccination problems are the topics that are complex and discussed on all platforms used by the world community for the purpose, and that efforts are being made to address the issues of safety, vaccine accessibility and respect for human rights.

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