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Towards Ethical Conception in Legal Regulation of Vaccination in the Russian Federation

SUMMARY

Today the ethical aspect became the cornerstone of all public discussion defining the success of vaccination all over the world. This situation had a basic influence on formatting the modern normative regulation connected with vaccination by the inclusion of the universal ethical principals in the legislative concept. It is also extremely important to reach an understanding and recognition of these fundamental bases among responsible professional community and public society in general. Another significant impact is also to get harmonization and solidarity between existing national legislation and international ones. These provisions defined the main objective of this article to analyze the role and value of the ethical component in the current legislation in the Russian Federation connected with vaccination. First, the significance of universal ethical principles in the process of vaccine's R&D and practical vaccination is presented (Chapter I). Secondary, the legal system of the Russian Federation is analyzed considering the compliance and the possibility of executing various ethical standards (Chapter II). Third, the author's research based on a questionnaire survey held among the various categories responsible for vaccination, an imbalance of knowledge, and the implementation of basic ethical-normative principles are shown (Chapter III). The main conclusion of the article is the confirmation of the compliance between Russian legislation and the universal principles of bioethics. At the same time, there is an urgent need for education and awareness in order to improve the scientific and practical achievements of

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vaccination and to get the real adaptation of an ethical concept among professional society, as well as to reach the public trust.

Keywords: Vaccination, universal ethical principles, Russian legal system, existence and realization.

1. Introduction

The main ethical challenges are associated with the vaccination, due to the need to overcome the conflict between the interests of the individual and society, accessibility, benefit/risk proportion, the principle of patients' voluntary involvement, information awareness, and respect to the personal autonomy. The ethical conception of vaccination should be sensitive to cultural and religious diversity; ensure special provisions for vulnerable groups; based on non-discrimination; social responsibility and solidarity.

Situations requiring the application of these universal ethical principles arise throughout the vaccination process, from the development of vaccines to their practical use. The link between scientific and technological breakthroughs at each new stage of R&D vaccines and practical vaccination with the need to resolve ethical conflict is well known and influence the activities of all involved structures: medical, legal, social, administrative, information, and public. The ethical concept of vaccination is in the field of view of leading international organizations such as WHO, CDC, UNESCO, which is widely represented in the literature and MEDIA and is one of the essential subjects of discussion between the civil and scientific community, the government, and religious denominations¹.

The special importance has the ethical concept of vaccination's law enforcement practices. The understanding of this reality became the main reason to present the ways for the realization of the ethical principles in the legal framework of the Russian Federation in this particular article.

2. Ethical Consideration of the Legal System

In the special document "Development of the Health Service", approved and came into force on 15.04.2014 by decision № 294, ed. 12.08.2017 by Government of the Russian Federation (RF), the following modern priorities are mentioned: improvement of the health service infrastructure, creation of the integrated

1 Pelčić G., Karačić S., Mikirtichan G.L., Kubar O.I., Leavitt F.J., Cheng-tek T. M., Morishita N., Vuletić S., Tomašević L. (2016) Religious exception for vaccination or religious excuses for avoiding vaccination, *Croat Med. J.*, № 57, 508–513.

prophylactic environment, increasing the quality of medical aid, and increasing performance standards of human medical resources².

The strategy determined by the Ministry of Health put the goals for the period 2016-2021, such as guaranteeing medical aid available, an increase of medical service efficacy corresponding to the prevalence of diseases, population needs, and pioneering medical technologies. The law laconically gives short-term tasks such as healthy lifestyle habits in population, prophylaxis of diseases, decreasing the mortality of the infectious diseases, decreasing their prevalence down to sporadic level, a realization of state programs of immunization both children and adults in order to reach epidemical well-being of the society. Awareness of all the points mentioned above presents a panoramic view of the ethical components in legal regulation in the Russian Federation, the vaccination being the most effective, economical and easily available means of infectious diseases prophylaxis, epidemics prevention, decreasing infectious prevalence and mortality. Vaccination is considered the most important part of medical aid in its own right, which implementation and quality are guaranteed by the State.

One can define only that immunization program could be successful, which is supported by wide vaccination of certain strata of community and causes a steady decline in morbidity or decrease in disease burden. Most frequently, total immunization involves children as a vulnerable group, which demands the strict following of ethics principles. It also raises the question of the restriction of personal autonomy. As any social help, it demands following such ethical principles as respect to a human being, autonomy and independence of the decisions, kindness, benefit/risk proportion, accessibility, and equity.

Under the current legislation and medical licensing, accessibility of vaccination is available in a medical institution with all forms of ownership. Vaccination is based, first and foremost, on the Constitution of the RF in Article 41.2. “In the Russian Federation federal programmers of protecting and strengthening the health of the population shall be financed by the State; measures shall be adopted to develop state, municipal and private health services; activities shall be promoted which facilitate the strengthening of health, the development of physical culture and sport, ecological and sanitary-epidemiological well-being”³.

The Federal Act “About sanitary and epidemiological wellbeing of population” № 52-FA (dated 30.03.1999, ed. 26.07.2019) determines the state’s level of responsibility, puts the prevention of epidemics and rectification of the consequences, as well as

2 “Development of the Health Service” (approved and came into force 15.04.2014 by decision № 294, ed. 12.08.2017 by Government of the Russian Federation).

3 Constitution of the RF, entry into force December 25, 1993, current edition: July 21, 2014.

prophylactic vaccination as a measure to prevent infectious disease evolving and spread⁴.

The Federal Act “About immune prophylaxis of infectious disease” 17.09.1998, № 157, article 4, (ed. 28.11.2018) says that the State gives guarantees about the accessibility of vaccination⁵. The State guarantees: accessibility of vaccination for citizens; free vaccination for those vaccines that are included in the National Calendar of vaccination and vaccination for the epidemic indication in the state and municipal health care system.

Besides the vaccines that are made in the RF, there is a substantial amount of overseas vaccines with no Russian equivalents, but are necessary to ensure epidemic safety. In this regard, after the corresponding procedure of control studies and approval in the country, they can be used in medical practice. The latter circumstance not only makes it possible to protect certain contingents but also expands the global resource of pharmaco-epidemiological experience as is recommended by the WHO⁶.

The main act that defines the schedule of vaccination both in a normal situation and during the epidemic outbreak is Order of Ministry of Health of RF (21.03.2014, № 125n (ed. 19.02.2019) “About the national calendar of vaccination and the calendar of vaccination during the epidemic outbreak”⁷. The schemata can differ, taking into consideration any new vaccines elaboration or recent data regarding the use of vaccines existing. The main basis of applying a vaccine is its medical instruction, approved by the National Health Service. Sanitary Rules of the Russian Federation regulate vaccination in different regions during the epidemic outbreak. The State Children and Adult Vaccination Planning System define the deadlines and amount of vaccine supply; they are centralized and strictly documented. This step can influence, however, the whole process. Taking into consideration specialties of production, certifying, and transportation of immune-biological samples, one should consider that timeliness of vaccination can only be provided by the stable presence on the market of several vaccines for protection against infectious diseases and, of course, by the progressive development and ameliorating of Russian vaccines production.

The serious obstacles to on-time vaccination are a medical exemption to the required immunization. Vaccination studies on chronically ill patients have enabled access to

4 The Federal Act “About sanitary and epidemiological wellbeing of population” № 52-FA dated 30.03.1999 (ed. 26.07.2019).

5 The Federal Act “About immune prophylaxis of infectious disease” 17.09.1998 № 157 (ed.28.11.2018).

6 Global Advisory Committee on Vaccine Safety, Quality and safety of vaccines, ranging from their development to administration to patients // WHO newsletter, 2005 - № 295. http://www.who.int/vaccine_safety/committee/en

7 Order of Ministry of Health of the RF “About the national calendar of vaccination and the calendar of vaccination during the epidemic outbreak” (21.03.2014 № 125n (ed. 19.02.2019).

different strata with minimizing medical exemption, which increases the percentage of vaccinated people⁸.

The specificity of the ethical principle of vaccine prevention (the benefit outweighs the potential harm) is that the effectiveness of vaccination should be looked upon in conjunction with safety. It consists of all stages of immunization, such as research and development, vaccine production, vaccine storage, the technique of vaccination, registration of adverse effects, and epidemical and economic analysis of its effectiveness.

There is a difference between vaccines and other safety standards of medical products because vaccines are usually applied to the healthy people (“*noli nocere*” principle). Therefore, only a very small percentage of side-effects are possible, and vaccines must have the highest safety standard as it enables the trust of society to vaccination.

Taking into consideration the entire mentioned above, one should appreciate the need for a feasible local framework concerning immunization and public health protection.

Vaccine production, testing, clinical use are strictly defined by the Global Advisory Committee on vaccine safety of the WHO according to which standards-compliant and legal base of the Russian Federation is embodied and fully completed. Such corpulent documentation is the witness of a highly complex process of vaccine prevention at every step with many medical specialists involved.

The most important part of work for ensuring safe vaccination is studying the negative side effects. All the vaccines are thoroughly studied before obtaining the license for a medical application, and in addition, each batch of licensed vaccine needs a quality certificate before it is released for sale. The patient involved in clinical research has special health insurance (Decree of the Government of the RF (13.09.2010, № 714). One has to highlight, that a huge amount of patients (10 000 and more) are required in the third stage of the clinical trial. Nevertheless, specific side effects may not be revealed. Therefore post-vaccination monitoring is needed to ensure benefit/risk proportion. This process is regulated by the Decree of the Government of the RF “About approving the regulations on the Federal service for supervision of healthcare” (30.06.2004, № 323; ed. 26.11.2019, № 1510, ar. 5.1.4. 5.1.7.) and the Order of the Ministry of Health and Social Development of the Russian Federation

8 Kostinova, M. P., ed. (2013) *Vaccination of the children with impaired health*, 4Mpress, 432.

regarding serious adverse reactions or unwanted adverse reactions when using drugs for medical use⁹.

The system of spontaneous notice about vaccines' negative side-effects is successfully applied around the world, including the RF. The voluntary consent is the basic ethical principle of medical aid in the RF and is reflected in the Constitution of the Russian Federation: "No one shall be subject to torture, violence or other severe or humiliating treatment or punishment. No one may be subject to medical, scientific and other experiments without voluntary consent" (The Constitution of the RF, Article 21.2). Nevertheless, the Constitution also states: "The rights and freedoms of man and citizen may be limited by the federal law only to such an extent to which it is necessary for the protection of the fundamental principles of the constitutional system, morality, health, rights and lawful interests of other people, for ensuring defense of the country and security of the State" (Article 55.3)¹⁰.

With regard to vaccination, this determines the absence of the legally prescribed obligation in the RF to vaccinate, and it provides liability for the absence of preventive vaccinations among citizens, as mentioned above in the Federal law (No. 157-FZ, 17.09.128998, ed.28.11.2018).

However, in some situations and areas of professional activity, vaccinations are mandatory, precisely because of the additional risks and effects on health and epidemic well-being. There is an official document (Decree of the Government of the RF No. 825, 15.07.1999 (ed. 24.12.2014) "On approval of the list of work, the implementation of which is associated with a high risk of contracting infectious diseases and requires mandatory vaccination." For example, these areas of activity for obvious reasons include medical and educational workers, veterinarians, etc. Specific conditions exist in the field of tourism, which are determined by the epidemic context of each country and international health standards. In a particular situation, the measures, suspension, or denial of entry are only possible if there is a threat of massive infectious diseases and the introduction of quarantine.

Patient's rights are stated in "About immune prophylaxis of infectious disease" 17.09.1998 № 157 (ed. 28.11.2018) and include the right to information, voluntary consent for vaccination, choice of physician, medical organization, vaccines; free vaccination and free medical aid should negative side-effects occur from vaccination;

9 Decree of the Government of the RF "About approving the Regulations on the Federal Service for Supervision of Healthcare" (30.06.2004, № 323, current edition: 26.11.2019, № 1510 (article 5.1.4. and 5.1.7.)) and the Order of the Ministry of Health and Social Development of the Russian Federation regarding serious adverse reactions, unwanted adverse reactions when using drugs for medical use.

10 The Constitution of the Russian Federation, entry into force December 25, 1 07993, current edition: July 21, 2014.

the refusal of vaccination, social support. Obtaining informed consent is the main duty of medical organizations and specialists after a feed-back dialogue between the patient and the medical specialist. As it is mentioned in Articles 3 and 11 by the above Federal Act, informed consent is the main principle of the vaccination in the Russian Federation, and according to the Order of the Federal Medical and Biological Agency (FMBA) of the RF of 30.03.2007 № 88 “About voluntary informed consent for medical intervention” (together with the “Instruction for filling in the forms of voluntary informed consent”), every patient must sign the informed consent form¹¹. This protects the personal autonomy. Nevertheless, an ethical dilemma occurs when parents and guardians realize their right to make a decision for their children, which, on the other hand, restricts the personal autonomy of the child.

Vaccination refusal is one of the patient’s rights. However, the causes of refusals should be thoroughly analyzed in order to find negative factors influencing it and the ways to prevent and eliminate it. The main reason influencing the decision is the confidence in medical specialists. Article 41.3 of the Constitution of the Russian Federation states: “The concealment by officials of the facts and circumstances posing a threat to the life and health of people shall entail responsibility according to the federal law”. The Constitution of the Russian Federation also states: “the labor and health of people shall be protected, a guaranteed minimum wages and salaries shall be established, state support ensured to the family, maternity, paternity and childhood, to disabled persons and the elderly, the system of social services developed, state pensions, allowances, and other social security guarantees shall be established” (Article 7.2). The Federal Act “About immune prophylaxis of infectious disease” 17.09.1998 № 157 (ed. 28.11.2018) and the Decree of the Government of the RF “About the procedure for paying state lump-sum benefits and monthly monetary compensation to citizens when they have post-vaccination complications”, dated 27.12.2000, № 1013 (ed. 05.09.2002, № 658; 08.04.2015, № 790), name social guarantees for those people who have negative post vaccination’s side-effects and complications, including benefit payments for the patient and his/her parents during the illness¹². One must notice that the red tape of obtaining these benefits is a substantial obstacle in vaccination in the RF.

It should be highlighted that the law in the RF refers especially to the rights of children. The Federal Act “About social guarantees of child’s rights in the Russian

11 The Federal Act “About immune prophylaxis of infectious disease” 17.09.1998 № 157 and the Order of the Federal Medical and Biological Agency of the Russian Federation of 30.03.2007 № 88 “About voluntary informed consent for medical intervention” (together with the “Instruction for filling in the forms of voluntary informed consent”) http://www.consultant.ru/document/cons_doc_LAW_87721/.

12 The Decree of the Government of the RF, dated 27.12.2000 № 1013, “About the procedure for paying state lump-sum benefits and monthly monetary compensation to citizens when they have post-vaccination complications” (ed. 5.09.2002, № 658; 08.04.2015, № 790).

Federation” (№ 124-FA 24.08.1998, article 6; ed.16.10.2019) states that the children’s rights in the Russian Federation are guaranteed by the Constitution of the Russian Federation in commensuration with accepted norms of international law and legal basis of Russia¹³.

The situations where the question of the right to a safe environment is discussed, are addressed in the Federal Act “About immune prophylaxis of infectious disease” (17.09.1998; № 157 ed. 28.11.2018), articles 5 and 8; the Federal Act “About sanitary and epidemiological wellbeing of population” (№ 52-FA; dated 30.03.1999, ed. 26.07.2019), article 10. Compulsory vaccination is used when the epidemic situation requires it, as the members of society have the right to a safe environment¹⁴.

3. Status of the questionnaire research

In order to study the opinion of pediatricians about ethical-normative and organizational problems of vaccination, we conducted a specially designed questionnaire to interview 250 pediatricians working in children’s clinics in St. Petersburg¹⁵. The results of the targeted survey showed the following. Of primary importance is the opinion of pediatricians on the effectiveness of vaccine prevention. The answer to this question indicated that 92.8% of them recognize that as many children as possible should be covered with vaccines. Only 7.2% of respondents expressed confidence that the vaccine always guarantees protection against infection. The next set of questions concerned the attitude of pediatricians to vaccination, as a mass preventive measure. Third of the respondents (38.6%) confirmed the belief that in the interests of the health of the child, it should be vaccinated; 36.1% of pediatricians demonstrated a cautious approach to administering vaccinations, noting their usefulness based on the condition of the child. A special point of view, causing serious concern, was expressed by 22.9% of respondents, defining their position as follows: it is better to vaccinate so that the vaccination coverage rate is sufficient and there are no complaints from the administration. A survey aimed at identifying the experience of post-vaccination reactions showed that the majority of pediatricians (64.1%) encountered post-vaccination reactions in children in their practice. In the event of post-vaccination complications, according to 52.2% of doctors, free treatment should be carried out in a specialized hospital, 13.1% consider it necessary

13 The Constitution of the Russian Federation, entry into force December 25, 1993, current edition: July 21, 2014.

14 The Federal Act “About sanitary and epidemiological wellbeing of population” № 52-ФЗ dated 30.03.1999 edited 26.07.2019.

15 Mikirtichan, G. L., Asatryan, A. Zh., Kubar, O.I. (2009) “Some ethical and organizational problems of vaccination” in *Problems of urban health*, Vishnyakova, N. I. and Epelman, B. V., eds. – St. Petersburg, 222-225.

to pay monetary compensation for the harm caused to health, and 27.8% suggest strengthening social protection of such persons.

Unfortunately, the study showed that, according to the answers of the doctors themselves, such a mandatory requirement as a thorough examination of the child before vaccination, finding out all the details of his condition, is fulfilled only by 50.9% of respondents. Considering the importance of informing parents about a child before vaccination, it became clear how pediatricians comply with this statutory requirement (Article 31 of the Fundamentals of the Law of the RF “On the Protection of Citizens’ Health” and mentioned above in the Federal Act “About immune prophylaxis of infectious disease” № 157, Article 5). The answers showed that only 15.1% of doctors provide complete information. At the same time, 98.1% of respondents ask for the consent of the legal representative of a child. It fulfills the requirement of fundamentals of the legislation of the Russian Federation on the protection of public health. According to the survey, the implementation of the constitutional right of a person to the integrity of his/her personality and the possibility of refusal of vaccination was presented as follows. Only 9.2% of the pediatricians surveyed recognize the right of parents, and 38.3% recognize the right of a child of school age to refuse to be vaccinated. In the event that parents refused vaccination, the reaction of the doctors was as follows: 8.5% of pediatricians calmly agreed with the arguments of the parents; 74.5% urged parents on the importance of vaccination; 10.6% threatened, calling the restriction measures: no medical note to the nursery, kindergarten; will not be accepted to school; etc. Some answers contained combined actions. A small number of respondents (7.8%) did not give any answer to this question.

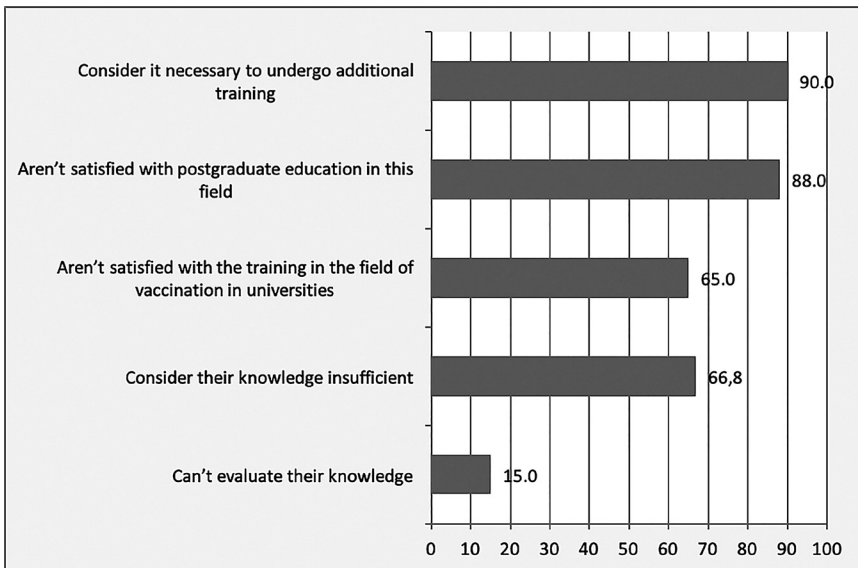
A special indication is medical personnel, a personal attitude to the possibility of using vaccines to protect them. During mass immunization, 23.3% of doctors are always vaccinated, 48.3% - as a rule, 20.7% - sometimes, 7.7% - never. Only 67.8% of the responding doctors regard the attitude of medical workers in relation to vaccine prevention as positive and 31.1% - as wary. When asked about the attitude of society towards vaccination, according to doctors, 29.7% of the population has a positive attitude towards vaccine prevention, the rest are wary (65.9%), and negative (4.4%). 71.4% of doctors are not satisfied with the existing system of informing the population about infection prevention measures. They are not satisfied with the fact that the media give a lot of negative, inaccurate information, and the vaccination propaganda system has not been established. In general, about 15% of doctors did not assess their knowledge, 66.8% considered them “insufficient”, 65% of respondents were not satisfied with the level of training in vaccination at universities, 88% were not satisfied with postgraduate education in this field. As a result, up to 90% of respondents considered it necessary to receive additional

training. Behind these figures, symbolizing insufficient knowledge, there are always mistakes that lead to non-compliance with the national immunization schedule, the use of false contraindications, the introduction of unwarranted withdrawals, and other violations discrediting vaccination and giving rise to criticism, mistrust, and growth of vaccination.

So, the survey materials clearly indicate the need for urgent measures to build public support and confidence in immunization programs through the implementation of active and persuasive information policy on the part of the state. Special research has a positive role to play, the purpose of which should be to identify objective indicators of the risk-benefit ratio of vaccination (medical, social, and economic). Of great importance are scientific developments in the field of improving vaccination approaches, aimed at reducing contraindications and ensuring an honest and transparent decision-making procedure regarding vaccination.

Extremely perspective and particularly connected with the main objective of this article is the special task to determinate the degree and level of awareness of medical workers involved in vaccination, what is directly connected with the availability, sufficiency and quality of the education. For this reason, special attention focused on the study of respondents' opinions about the sufficiency of knowledge on this subject and the need for additional education (Fig. 1).

Figure 1.



Physicians' opinions on the level of their knowledge in the field of vaccination
(per 100 respondents)

These data require the improvement of the education system, both in the field of vaccine prevention, as well as in knowledge, understanding and implementation of legislation in this area. In this frame, it is important to consider that until 2013, only nurses received specialized vaccination training, and special training of doctors was not required, which, of course, characterizes the result of the study.

Licensing of medical activities for the vaccination became a separate type of medical care in the Russian Federation from the existing order of the Ministry of Health of the RF (11.03.2013, № 121n.). As part of this order, all medical personnel involved in vaccination, both nurses and doctors (pediatricians, family doctors, and therapists), should have specialized training. The requirement for special training for ‘vaccine providers’ was further enshrined in a series of subsequent regulatory documents (Order of the MH of the RF, 21.11.2014 № 125n, ed. 24.04.2019 “On the approval of the national calendar of preventive vaccinations and the calendar of preventive vaccinations according to epidemic indications”). According to this document, the training program includes knowledge of the regulations for the use and arsenal of vaccines, the organization, and the technique of vaccination, the provision of medical care in emergency or emergency form. The introduction of these measures and the current national system of continuing education with the mandatory inclusion of medical law gives the prospect of optimizing knowledge on vaccine prevention.

4. Conclusion

In the Russian Federation, there is a legal framework fully capable of ensuring the quality and effectiveness of each vaccination stage and guaranteeing compliance with universal ethical principles. Nevertheless, there are a number of unsolved problems, most of all associated with the need to increase the regulatory and humanitarian component of educational and informational programs. On the one hand, the emphasis should be placed on the legal and ethical long-term education of all professionals involved in the vaccination process. On the other hand, it is necessary to develop information sources in order to implement educational programs on vaccination for the population and the creation of open and qualifying consulting resources for building confidence and a positive perception of vaccination. These measures can increase adherence to vaccination and thereby provide a better profile of infectious diseases and increase the level of epidemic well-being.

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Internet Links

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Prema etičkom poimanju zakonskog propisa o cijepljenju u Ruskoj Federaciji

SAŽETAK

Danas je etički aspekt postao kamen temeljac svih javnih rasprava koje definiraju uspjeh cijepljenja u cijelom svijetu. Ova je situacija imala bitan utjecaj na oblikovanje suvremenog normativnog propisa povezanog s cijepljenjem uključivanjem univerzalnih etičkih načela u zakonodavni koncept. Također je izuzetno važno postići razumijevanje i prepoznavanje ovih temeljnih osnova između odgovorne profesionalne zajednice i javnog društva općenito. Drugi značajan utjecaj je također usklađivanje i solidarnost između postojećeg nacionalnog zakonodavstva i međunarodnog zakonodavstva. Navedene odredbe definirale su glavni cilj ovog članka, a on je analiziranje uloge i vrijednosti etičke komponente u trenutnom zakonodavstvu Ruske Federacije povezane uz cijepljenje. Prvo je prikazan značaj univerzalnih etičkih načela u procesu istraživanja i razvoja cjepiva i praktičnog cijepljenja (I. poglavlje). Kao drugo, pravni sustav Ruske Federacije analizira se uzimajući u obzir usklađenost i mogućnost provođenja različitih etičkih normi (II. poglavlje). Treće, prikazano je autorovo istraživanje temeljeno na anketnom upitniku provedenom među različitim ispitanicima odgovornim za cijepljenje, neravnotežu znanja i primjenu osnovnih etičko-normativnih načela (III. poglavlje). Glavni zaključak članka je potvrda usklađenosti između ruskog zakonodavstva i univerzalnih načela bioetike. Istodobno, postoji hitna potreba za obrazovanjem i osvješćivanjem radi poboljšanja znanstvenih i praktičnih dostignuća cijepljenja i postizanja stvarne prilagodbe etičkog koncepta među profesionalnim društvom, kao i postizanja povjerenja javnosti.

Ključne riječi: cijepljenje, univerzalna etička načela, ruski pravni sustav, postojanje i realizacija