

Legal regulation of personalized medicine in the agricultural sector: the experience of Russia

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Abstract. This study's topic's relevance is due to the rapid development of genetic research, when diagnostics, prevention, and treatment are carried out through the study of nucleic acids and their expression products – RNA and proteins. Predictive (personalized) medicine (PMM) has become a preventive trend in molecular medicine, understood in different ways. However, its generally accepted features recognize the individual nature of treatment (each person's genome is individual). The prophylactic focus of medicine (analysis of the genome is possible at any stage of ontogenesis, long before the disease's onset) is very important. In carrying out genetic certification, the need to find a legal solution to existing or projected problems is actualized. Legal science is designed to address the issues of protecting human rights in the process of genetic certification, countering discrimination, and other possible violations of constitutional values. The issues raised in the article acquire particular importance in the context of the covid-19 pandemic. Mobility and speed of decision-making require an appropriate legal approach to telemedicine, which will provide the population with high-quality and professional medical care. Besides, it seems reasonable to observe the balance of human rights and freedoms when using the institution of genetic certification and telemedicine

1 Introduction

The modern state of social development proclaims the biotechnological revolution period, which entered the age of convergence and digitalization as discussed by Stepenko V., etc. [1]. Further studies are tightly connected with creating information databases, which serve as the basis for genomic research, biological informatics, telemedicine, and other scientific spheres. The achievements of biotechnologies and digitalization entail the emergence of personalized the Complex Program for the Development of Biotechnologies in Russia until 2020, approved by the Russian Government № 1853 p-P8.

The analysis of approaches to personalized medicine allows us to reveal the general discourse. Personalized medicine represents a sphere of the public health sector, based upon integrated, coordinated, and individual patient-related approaches to analyzing disease appearance and progression, as mentioned by Chan I.S. and Ginsburg G.S. [2].

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Personalized medicine begets a new form of the public health sector, which demands philosophical, ethical, medical, legal explication and analysis.

This article introduces a view of personalized medicine through the scope of the law and digital technologies.

In Russia, one of the priorities for scientific and technical development is the shift towards personalized medicine, the high-tech public health sector, and health conservation techniques, including the rational use of pharmaceuticals (primarily – antibacterial drugs) (The Decree of the Russian President of December 1, 2016, № 642 “On the Strategy of Scientific and Technological Development in the Russian Federation”). The concept for predictive, preventive, and personalized medicine has been adopted, which is oriented towards the availability of personalized medical aid for the needs of early (pre-symptomatic) forecasting of diseases and their prevention; towards upgrading the efficiency of traditional treatment using their personalized application or using personally designed products (pharmaceuticals). That is regulated by order of the Russian Ministry of public health of April 24, 2018, № 186 “On the Approval of the Concept for Predictive, Preventive and Personalized Medicine.”

The core elements of personalized medicine in Russia are genetic passportization and telemedicine.

2 Methods

We have used a qualitative research methodology, linked to interpretive or comprehensive paradigm, approach characterized by analyzing reality using several data collection methods proposed by Maxwell [3]. In qualitative research, through interviews, life histories, case studies, or documentary analysis, the researcher can merge his observations contributed by others [4]. A statistical method was applied using the data of PJSC "Rossostrakh" in terms of the dynamics of the appeal for telemedicine services, taking into account the federal structure of the state shown in Fig. 1, 2, and 3.

3 Results

Enforcement of rights and freedoms when applying the institute of genetic certification. The growth of scientific and technological progress, the fusion of information and biotechnology lead to the renewal of the human rights catalog, as discussed by Tikhomirov Yu.A. [5]. On the one hand, the active introduction of these technologies is associated with the transformation of human and civil rights established at the constitutional and international level (the right to freedom and personal integrity, personal dignity, etc.), and on the other, with the emergence of new rights (somatic rights, reproductive rights a person, the right to a dignified death, etc.) as discussed elsewhere [6].

The inextricable link between a person's rights and the internal, spiritual component has been repeatedly addressed in philosophical studies, the emphasis in which is placed on the careful consideration of moral attitudes in law. The modern philosopher F. Fukuyama, examining the problem of human rights, points out that “in the last thirty years the industry of rights has grown faster than the Internet in the late nineties of the twentieth century” and highlights the rights of animals, women, and children, the rights of people with defects and limitations, human rights, the right to life, the right to death, the rights of the accused and the rights of victims [7].

The line between moral and ethical attitudes and law in matters of euthanasia, personal integrity is very mobile. These problems reflect “friction and contradictions that arise between the moral principles of a given society and legal norms, the purpose of which is to

consolidate specific rights and obligations [8]. “Exploring moral dilemmas, Raymond Wax notes [9] that they cannot be resolved with the slogans of “right to death,” “autonomy,” “self-determination,” or “sanctity of life,” since they are complex enough and the courts are not always fair arbiters in resolving them.

At the present stage, a broad international base of documents has been formed, aimed at protecting human dignity and guaranteeing everyone, without exception, respect the integrity of the individual and other rights and fundamental freedoms in connection with applying the achievements of biology and medicine. Among the international documents - the Convention for the Protection of Human Rights and Dignity of the Human Being concerning the Application of the Advances in Biology and Medicine: the 1997 Convention on Human Rights and Biomedicine, the 2005 Universal Declaration Bioethics and Human Rights, etc.

For example, the 2003 International Declaration on Genetic Data (Resolution of the General Conference of UNESCO N 32C / 15, 32nd session of the GC of UNESCO (2003)) defines human genetic data as information about individuals' heritable characteristics obtained through nucleic acid analysis or other scientific analysis. So, when studying genetic data, one should consider their following features: the possibility of indicating the manifestations of a person's genetic predisposition; have a significant impact over several generations on the family, including descendants, and in some cases, on an entire group of individuals; contain information, the meaning of which may not be known at the time of collection of biological samples; be culturally relevant to individuals or groups of individuals.

Further directions of research in the field of human rights and genetic information, it seems, should be determined by the need to separate as an independent - the right to genetic inviolability and the development of an appropriate mechanism for its protection. This thesis's objectification is such specific genetic information features as to its confidentiality, exclusivity, inalienability from a person, the inadmissibility of its disclosure without a person's consent, etc.

According to article 41, p.1 of the Russian Constitution, every person has a right to health protection and medical care (aid). Medical care in public and municipal hospitals is free for all Russian citizens.

The right to free medical care was provided by the USSR Constitution of 1977. However, the implementation of this right is somewhat tricky. The matters of free medical care arise sharply due to the transition towards personalized medicine in the direction of genetic passportization of Russia's population.

According to the Decree of the Russian President of March 11, 2019, № 97, the Basic Principles of the Russian State Policy in the Field of Chemical and Biological Security until 2025 and the Near Future were established. The Decree outlines that to monitor chemical and biological hazards, one should “conduct genetic certification of the population taking into account legal framework for the protection of human genomic data and draw up a genetic profile of the population.” The creation of “conditions for genetic certification of population and the development of screening techniques for human, animal and plant gene pools” is presumed.

It is proposed to create a national bank of blood serum and develop an information-analytical system for monitoring infectious diseases.

The following factors mainly determine the expected positive results from the implementation of personalized medicine (including genetic passportization).

Firstly, the development of knowledge upon etiology of various diseases allowed discovering that certain diseases originate from a particular organism's genetic peculiarities and inheritance – hemophilia.

Secondly, a particular organism's genetic peculiarities determine the exact reaction against treatment (for instance, the so-called paradox reactions when a medication causes opposite effects). Today in Russia, the unique targeted pharmaceuticals for treating several diseases, connected with the regulation of specific human genes' activity, are being applied successfully.

Thirdly, the severity of a disease progression is often dependent upon genetics. For instance, specific genetic mutations over mannose-binding lectin (protein, engaged in immunity protection – its activity depends upon genetic factors on 96 percent) may cause higher risks of respiratory infections or their aggravation.

The following factors determine the risks of personalized medicine. Along with providing financial availability of genetic testing, one should pay attention to protecting human somatic rights. The main question is – whether passportization should be imperative to secure national security and epidemic prevention. We deem that the priority should be given to an individual's right to decide the legal fate of his own body. However, this issue demands further legal support. Hence the law shall mitigate all possible risks of rights violation.

Apart from that, the Russian President's mentioned Decree provides no details over the definition of “genetic certification.” Is it a judicial genetic passport or a more solid document, which states potential risks for human health?

The regulation of the Allied state of May 22, 2016, № 12 “On the Concept of Scientific and Practical Program of the Allied State” provides for a task to develop genomic technologies for the manifestation of individual vulnerability to socially significant diseases (cancer and cardiovascular diseases) and mental instability. Moreover, the mentioned program determines genetic locus and intravital modification of DNA sequences, affecting psyche and behavior in extreme conditions. Practically a database of genotype is being created.

Such systematization, as well as genetic passportization, provides both opportunities and risks. Thus, the matters of protecting genetic information are arising. It is vital to secure it from unethical use. Today the mentioned questions remain unresolved in the Russian legislation.

Worldwide, the need to reduce face-to-face consultations without compromising the quality and access of essential health services has revitalized telemedicine and brought it to the forefront in the era of coronavirus disease 2019 (COVID-19) [10]. A similar practice has been recorded in the Russian Federation (see Table 2). In addition, this practice takes into account the federal nature of the Russian Federation (see Fig. 3). Discussions on telemedicine's necessity and feasibility have pervaded across a range of medical specialties and care settings. Health systems have introduced regulatory flexibilities and incentives to encourage adoption and implementation, coordination from providers and technology companies [11, 12].

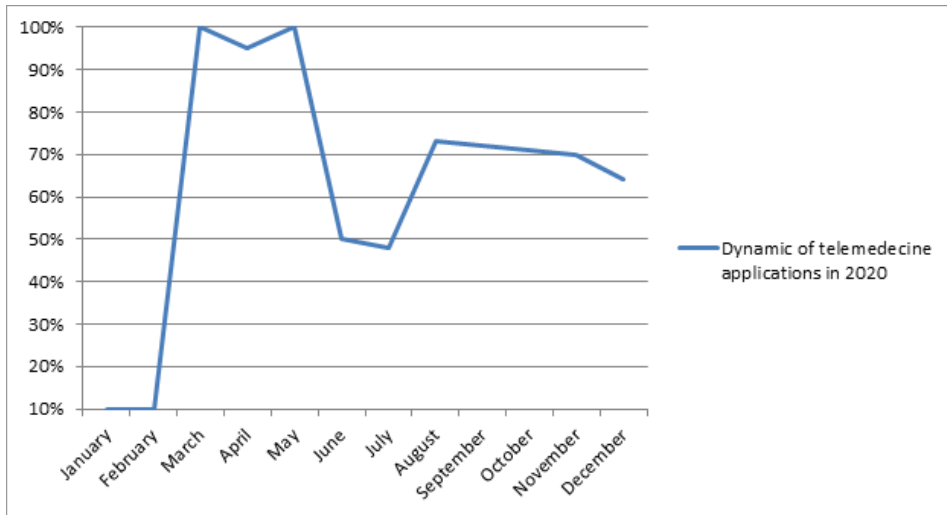


Fig. 1. Dynamics of telemedicine applications in 2020.

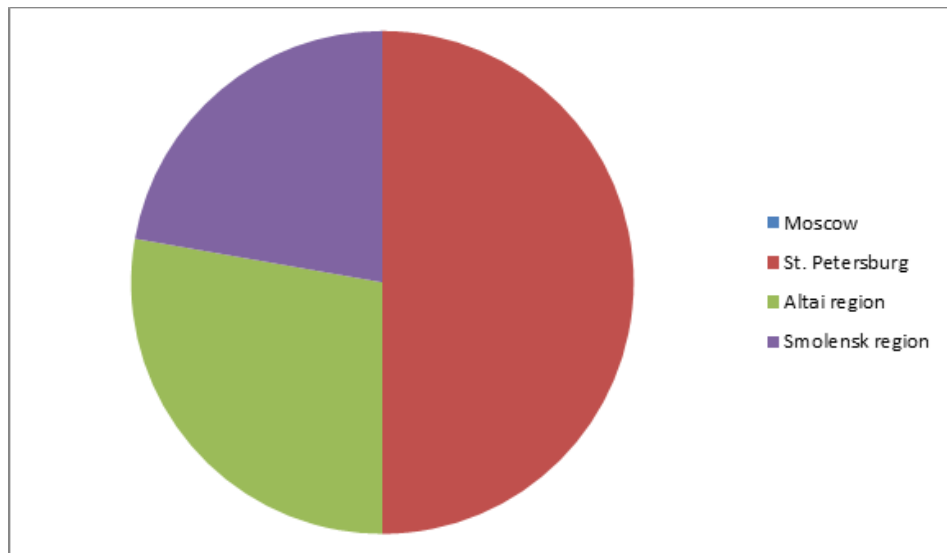


Fig. 2. Telemedicine in the constituent entities of the Russian Federation.

Telemedicine, a term coined in the 1970s, literally means “healing at a distance,” which signifies using ICT to improve patient outcomes by increasing access to care and medical information. Recognizing that there is no one definitive definition of telemedicine – a 2007 study found 104 peer-reviewed definitions of the word (2) – the World Health Organization has adopted the following broad description: “The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for the diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.”

The term “telemedicine” was legally provided for the first time in the Concept of the Development of Telemedicine Technologies in the Russian Federation. Currently, the relevance of telemedicine technologies' development is of particular importance in

connection with the amendments to the Constitution of the Russian Federation in 2020 [4]. In addition, in 2020, the Russian Federation ascertained a significant interest in the applying of telemedicine (see Fig. 3).

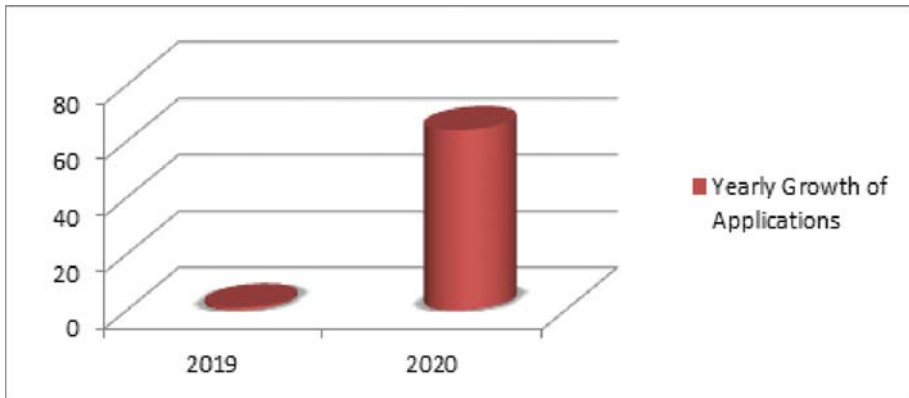


Fig. 3. Dynamics of the provision of medical care using telemedicine technologies.

According to the constitutional novelties, the issues of the joint jurisdiction of the Russian Federation and the constituent entities of the Russian Federation include the coordination of health issues, including ensuring the provision of affordable and high-quality medical care, preserving and strengthening public health, creating conditions for a healthy lifestyle, and forming a culture of a responsible attitude of citizens to their health. Local self-government bodies, as elements of public authority, within their competence, ensure the availability of medical care, as noted Pomazanskiy A. [13].

Telemedicine (remote medicine), according to the Concept of the Development of Telemedicine Technologies in the Russian Federation, includes the following elements: diagnostic consulting, management, educational, scientific, and information services in the field of the public health sector, implemented using telecom.

It is important to note that the Russian legislator used an expansive telecom interpretation in the public health sector.

However, sometime after, the legislator narrowed the definition and the scope of telemedicine down.

In 2017 the Federal law “On basic principles for protecting public health in the Russian Federation” gained a new section, “Peculiarities of medical care, provided using telemedicine technologies.” The law mentioned defines the following spheres of applying telemedicine technologies:

- remote cooperation of medical staff;
- remote cooperation between medical staff and patients or their representatives;
- identification and authentication of the mentioned people;
- documentation of the measures taken upon consultations, concilium, remote patient monitoring.

The main goal of implementing information technologies into clinical medical practice lies in enhancing the quality of human life through providing a due level of health protection [14, 15].

According to the order of the Russian Ministry of public health of November 30, 2017, № 965n “On the Approval of the Order for Organizing and Providing Telemedicine Technologies” (p. 47, 48), while consulting patients and their representatives, the nursing physician may correct deployed treatment for the patient, prescribe pharmaceutical recipes in electronic form under the condition that a physician had determined the diagnosis and had made prescriptions over a prior personal examination or consultation.

The ability to make medical prescriptions in an electronic form is a legal novelty [16].

4 Discussion

In the regions of the Russian Federation, the electronic prescription is now available. In the Northern administrative district of Moscow from May 15, 2013, till October 31, 2013, the practical use of the Single Medical Information-Analytic System of Moscow took place. This system is intended for making electronic prescriptions over pharmaceuticals, medical appliances, and unique products for medical nutrition (for disabled children) addressed to citizens entitled to procure public social assistance free of charge or at a 50% discount (The Order of the Department for Public Health of Moscow of July 3, 2013, № 666 “On the experimental use of the Single Medical Information-Analytic System of Moscow, designed for making electronic prescriptions”).

During the experiment, a Temporary order for making electronic prescriptions using the system took effect.

The Russian legislation provides for a narrow approach for defining telemedicine, which considers it as clinical medical care. However, the following issues are beyond the scope: remote education, clinical studies; management solutions; medical guides; electronic drugstores.

We should also note the high practical relevance of the patients' participation in making decisions concerning their health. The increasing role of the patient in managing his electronic records over health should ensure the citizens' rights to acquire information concerning their health and create an environment for personalized medicine.

The risks of implementing telemedicine technologies in Russia relate to conservative legal regulation:

- licensing;
- using a single system for identification and authentication;
- having a vast amount of data to be provided by a relevant medical organization;
- having a multilevel system for making electronic prescriptions;
- lacking well-defined rights of medical staff, patients, and their representatives.

5 Conclusion

The Basic principles of state policy and other program documents in Russia show an urge to develop personalized medicine. However, at present times, there is the mere experimental practice of using telemedicine, while creating a genetic database of Russian citizens is still at its earliest stage.

In most foreign countries, there is no normative consolidation of the concept of genetic certification. If by the genetic certification we mean the totality of the data of the genetic test of the human genome or the corresponding document of the medical plan (genetic passport), then in many countries, the category of genetic information or genetic data is suitable for such a description, which, in turn, have a regulatory framework and a special legal regime.

In carrying out genetic certification, it is crucial to recognize the right to genetic integrity and develop an appropriate protection mechanism. This thesis's objectification is such specific genetic information features as to its confidentiality, exclusivity, inalienability from a person, the inadmissibility of its disclosure without a person's consent, etc.

References

1. V. Stepenko, O. Chernova, Y. Bokov, Y. Truntsevsky, *Jour. of Adv. Research in Dynamical & Control Systems* **12(02)**, 215-220 (2020)
2. I.S. Chan, G.S. Ginsburg, *Annual Review of Genomics and Human Genetics* **12**, 217-244 (2011)
3. J. Maxwell, *Handbook of Applied Social Research Methods* (SAGE Publications Inc., California, United States, 2009) <https://doi.org/10.4135/9781483348858.n7>
4. T.Y. Khabrieva, *Herald of the Russian Academy of Sciences* **90(3)**, 273-282 (2020)
5. Yu.A. Tikhomirov, *Herald of the Russian Academy of Sciences* **90(6)**, 772-778 (2020)
6. A. Abashidze, M. Solntsev, *Moscow Journal of International Law* **1**, 69–82 (2009)
7. F. Fukuyama, M. Levin, *Our posthuman future. Consequences of the biotechnological revolution* (Lux. AST, M., 2004)
8. D. Lloyd, *The Idea of Law: Repressive Evil or Social Necessity?* (Knigodel, M., 2009)
9. R. Wax, *Philosophy of Law. Short introduction* (M., 2020)
10. M.A. Lavrik, *Siberian legal bulletin* **3**, 16-26 (2005)
11. J. Vidal-Alaball, R. Acosta-Roja, N. Pastor Hernández, et al, *Aten Primaria* **52(6)**, 418-422 (2020)
12. M. Alvandi, *The American Journal of Accountable Care* **5(1)**, e1-e5 (2017)
13. A. Pomazanskiy, V. Sevalnev, *Journal of Advanced Research in Law and Economics* **9(5)**, 1754-1758 (2018)
14. O.E. Starovoitova, *Legal mechanism for the implementation and protection of somatic human and civil rights in the Russian Federation (historical, legal and theoretical analysis): Dis. Dr. jurid. sciences* (SPb, 2006)
15. Yu.N. Harari, *21 lessons for the 21st century* (Sinbad, M., 2019)
16. N.V. Putilo, *Information Technologies in the Sphere of Health Protection: Commentaries on Russian Federal Law No. 242-Fz, July 29, 2017* (Prospekt, Moscow, 2019)