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INTERNATIONAL LEGAL REGULATION OF THE USE OF ARTIFICIAL INTELLIGENCE IN THE FIELD OF MEDICINE

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LIST OF ABBREVIATIONS AND SYMBOLS

WMA	The World Medical Association
WHO	The World Health Organization
WIPO	The World Intellectual Property Organization
WTO	The World Trade Organization
Civil Code	Civil Code of the Russian Federation
EEU	The Eurasian Economic Union
EU	The European Union
AI	artificial intelligence
ILO	The International Labour Organization
ITU	The International Telecommunication Union
STP	scientific and technological progress
UN	The United Nations
OECD	The Organisation for Economic Co-operation and Development
CL RF	Collection of Legislation of the Russian Federation
CIOMS	Council for International Organizations of Medical Sciences
CIS	The Commonwealth of Independent States
MDSS	medical decision support system
UNESCO	The United Nations Educational, Scientific and Cultural Organization
GDPR	General Data Protection Regulation
IEEE	The Institute of Electrical and Electronics Engineers
IMDRF	The International Medical Device Regulators Forum
ISO	The International Organization for Standardization
NEMA	The National Electrical Manufacturers Association
U.S. FDA	The United States Food and Drug Administration

INTRODUCTION

Relevance of the research topic. Artificial intelligence (hereinafter – AI), being one of the advanced technologies of the fourth industrial revolution[1], leads to the transformation of relations in all spheres of society, including health care and law[2]. As noted in the Foreign Policy Concept of the Russian Federation, approved on 31.03.2023[3], at present, due to the development and spread of new technologies (including AI), there is a structural reorganization of the world economy, which is being transferred to a new technological basis. Intelligent technologies are revolutionizing the capabilities of medicine, biology and pharmacology, bringing the capabilities of healthcare to a new qualitative level.

AI is a highly effective tool due to its autonomous operation (including the ability to make unprogrammed decisions in advance) and learning ability, therefore, the use of intelligent algorithms (hereinafter referred to as algorithms) can expand the arsenal of medical manipulations, efficiency of delivery, accessibility of medical care and universal health coverage (see Appendix A).

At the same time, these properties of AI systems cause unpredictability of algorithms' behavior, create the risk of uncontrolled development and purposeful use of AI to harm human life and health, which causes serious problems of socio-economic, ethical and legal nature (see Appendix B). Moreover, intellectual software is one of the dual-use technologies that can be used in the development of armaments and military equipment (clauses 5.4.2.3-5.5.3.2 of the List of Dual-Use Goods and Technologies approved by Decree of the Government of the Russian Federation dated 19.07.2022 № 1299[4]), which led to the establishment of export control of the Russian Federation with regard to AI developments in order to prevent the use of their destructive potential.

In this regard, the problem of ensuring control over the development and use of intelligent algorithms is currently topical. Thus, in March 2023, more than a thousand experts in the field of AI and IT industry, including I. Musk (founder, CEO of SpaceX and Tesla) and S. Wozniak (co-founder of Apple Computer), signed an open letter calling for a 6-month moratorium on the creation of new versions of

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[1] Laptev, V.A. The concept of artificial intelligence and legal responsibility for its work / V.A. Laptev // Law. Journal of the Higher School of Economics. 2019. № 2. P. 80.

[2] Ioyrysh A.I. Scientific and technological progress and new problems of law: a monograph / A.I. Ioyrysh. Moscow: Intern. relations, 1981. P. 8.

[3] On Approval of the Concept of the Foreign Policy of the Russian Federation : Decree of the President of the Russian Federation of 31.03.2023 № 229 [Electronic resource] // PRAVO.GOV.RU: official Internet portal of legal information. 2023. March 31. URL: http://publication.pravo.gov.ru/Document/View/0001202303310007 (date of access: 30.05.2023).

[4] On Approval of the list of dual-use goods and technologies that can be used in the development of weapons and military equipment and in respect of which export control is exercised : Resolution of the Government of the Russian Federation of 19.07.2022 № 1299, ed. of 26.01.2023 // CL RF. № 30. Art. 5630.

strong AI[5] in order to develop an effective system for predicting risks and ensuring control over the development and consequences of the introduction of intelligent technologies[6].

The creation of a control system requires the development of a special legal regime for AI, as well as the adaptation to the conditions of digitalization of already existing legal institutions and procedures, such as obtaining informed voluntary consent to medical intervention, control over the circulation of medical devices, tort liability for harm caused by algorithms, etc. However, at the moment there is no holistic legal regulation of AI (both international and domestic), which is at the stage of formation and is fragmentary in nature[7]. There is no special legal regime for medical AI at all.

The relevance of the present dissertation research is conditioned by the following:

1. Transition to advanced digital and intelligent production technologies, as well as personalized medicine and high-tech healthcare, including through the creation of systems for processing large amounts of data, machine learning and artificial intelligence is one of the priorities of scientific and technological development of the Russian Federation until 2025-2030[8].

2. The achievements of scientific and technological progress often not only bring benefits and comfort, but also generate risks associated with increasing technological inequality, the threat of monopolization of the technology market and interference in the internal affairs of States, and using dual-use technologies to violate fundamental human rights and freedoms. These global problems cannot be solved by individual States. As rightly noted in paragraph 12 of the Concept of Foreign Policy of the Russian Federation: «Only the unification of potentials and good faith efforts of the entire international community on the basis of a balance of forces and interests can provide an effective solution to the numerous problems of our time, the peaceful progressive development of large and small states and humanity as a whole».

3. Due to the transboundary nature of modern information technologies, international legal regulation is of particular importance, as only international law is able to ensure the harmonization of international and domestic law-making and the pooling of material, organizational, financial, labor, and intellectual resources of individual countries to ensure the integrated development of technologies and solve the problems caused by the spread of AI in medicine – a complex phenomenon that combines a significant creative and creative potential.

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[5] Strong AI is generally defined as an algorithm that has the ability to perceive and understand the world around it, analyze information, learn, make decisions, and solve problems in a wide range of application domains.

[6] Pause Giant AI Experiments: An Open Letter [Electronic resource]: Open Letter // FUTUREOFLIFE.ORG: official website of Future of Life Institute. [Cambridge], 2023. URL: https://futureoflife.org/open-letter/pause-giant-ai-experiments/ (date of access: 30.05.2023).

[7] Willems A. Of Binding Provisions and Trust Marks; Roadmap to a Global Legal Framework for the Digital Economy / A. Willems, M. Kamau // Legal Issues of Economic Integration. 2019. Vol. 46. № 3. P. 226.

[8] On the Strategy for Scientific and Technological Development of the Russian Federation : Decree of the President of the Russian Federation of 01.12.2016 № 642, ed. of 15.03.2021 // CL RF. 2016. № 49. Art. 6887.

4. Chaotic rule-making by states, international organizations and integration associations can complicate the development of controlled and safe AI, which necessitates the development of sources of international law that would lay the foundation for both the harmonization of the existing and the development of new, consistent and consistent domestic regulation of relations complicated by AI.

5. The incompatibility of technical parameters of intellectual developments, information-exchange processes, security requirements and differences in procedures for the use of AI systems may make it impossible to use AI technologies in cross-border relations, as well as the international exchange of medical goods (medicines, medical devices) and services in the framework of international trade turnover.

6. Scientific and technical progress in the field of intellectual technologies is developing rapidly. Therefore, its legal regulation should be built in such a way that when new scientific discoveries and achievements appear, it is not necessary to develop legal regulation anew.

7. Increasing the effectiveness of international cooperation in the field of health care and countering its politicization, including within the framework of international organizations, as well as increasing the effectiveness of international scientific research in the field of health care, primarily aimed at the development and introduction of new means of prevention, diagnosis and treatment of diseases, is one of the main tasks for achieving the strategic goals of the foreign policy of the Russian Federation (paragraphs 17 and 42 of the Concept of Foreign Policy of the Russian Federation)[9].

For this reason, the development of a unified legal regime for the use of AI technologies based on a system of special legal principles, adaptation of existing legal institutions regulating medical manipulations, ensuring the confidentiality of personal data and control over the circulation of medical devices, as well as the intensification of international cooperation will lead to a significant increase in the pace of technological development and introduction of safe and controlled algorithms into the medical practice in respect of which the risk of illegal use of dual-use technologies and goods will be excluded.

Drawing attention to the importance of artificial intelligence for asserting the state's priority in scientific and technological development, President of the Russian Federation V.V. Putin noted that leadership in the field of intellectual technologies can ensure the state's advanced position on the world stage[10]. Earlier, the Russian President expressed his conviction that «new solutions that change the world

[9] We draw attention to the fact that this task, which was set in order to achieve the strategic goals of the foreign policy of the Russian Federation, is not the only one and can be realized only in conjunction with the other tasks specified in paragraph 17 of the Concept of Foreign Policy of the Russian Federation, including the development of mutually beneficial and equal cooperation with constructive foreign States and their associations (subparagraph 4) and countering the anti-Russian activities of unfriendly foreign States and their associations (subparagraph 5). See: p. 27-28 of the dissertation research.

[10] Monopolist in the field of artificial intelligence may become the ruler of the world [Electronic resource] // TASS.RU: TASS News Agency. 2019. May 30. URL: https://tass.ru/ekonomika/6489864 (date of access: 30.05.2023).

can be created only through close cooperation, based on trust and high ethical standards. This applies to all technological areas, but especially to artificial intelligence»[11].

However, international cooperation not formalized by international law, in the absence of a mechanism to monitor the proper implementation of international obligations on a non-discriminatory basis, can lead to abuses by individual participants in such cooperation to interfere in the internal affairs of States. For this reason, it is fundamentally important to initiate a process of elaboration by the subjects of international law of a special international legal regulation fully consistent with the principles of international law.

Further delay will lead to fragmentation and weakening of the international legal system, as well as create the risk of «monopolization» of the international standard-setting in the field of artificial intelligence for individual states, which will provide ample opportunities for abuse and selective application of international legal norms. Such a situation not only hinders the progressive development of international law and scientific and technological progress, but also contradicts one of the main national interests of Russia in the foreign policy sphere (paragraphs 15 and 23 of the Concept of Foreign Policy of the Russian Federation).

Degree of development of the research topic. The inclusion of AI in legal discourse as a topical problem requiring the attention of researchers occurred in the early XXI century, but most actively – only in the second decade of the twenty-first century.

Despite a significant number of scientific works devoted to the fundamental issues of legal regulation of AI (legal personality, liability, risk of uncontrolled development) and modern technologies in general, there are practically no legal studies devoted to the special legal regime of AI in medicine, pharmacology and public health. The solution of problems related to the adaptation of the existing and creation of new international legal regulation of the use of AI in medicine requires complex and interdisciplinary research, which is currently lacking as well.

Certain issues that became the subject of consideration in this dissertation research were previously addressed in the works of S.V. Bakhin («The Impact of New Technologies on Modern Private International Law», Chapter 5 of the monograph «Modern Private International Law in Russia and the European Union», 2013), N.A. Dmitrik («The Limits of Legal Regulation in the Digital Age», 2018), A. Willems and M. Kamau («Of Binding Provisions and Trust Marks; Roadmap to a Global Legal Framework for the Digital Economy», 2019), A. Keisner, D. Raffo, and S. Wunsch-Vincent (Robotics: Breakthrough Technologies, Innovations, Intellectual Property, 2016), S.V. Strygina («Ethical Foundations of Information Technology Implementation in Risk Society», 2021), M. Hildebrandt («The Artificial Intelligence of European Union Law», 2020).

[11] Conference on Artificial Intelligence [Electronic resource] // KREMLIN.RU: official site of the President of Russia. 2022. November 24. URL: http://www.kremlin.ru/events/president/transcripts/69927 (date of access: 01.10.2023).

The problems in the field of interstate relations on health protection have also been insufficiently researched so far. In this context we can note the works of A.I. Ioyrysh, who first considered the issues of legal regulation of scientific and technological progress (hereinafter – STP) in the field of medicine, biology and pharmacology («Scientific and Technological Progress and New Problems of Law», 1981), V.S. Mikhailov – on the cooperation of states in the field of international health care («History of International Health Law», 1984), the dissertation of S.V. Bakhin, which investigated the issues of human rights protection in connection with the spread of STP achievements in the field of medicine («Scientific and Technological Progress and New Problems of Law», 1981).

Legal studies touching upon the problems of legal regulation of AI in the field of medicine are extremely rare. We should mention the works of M.S. Varyushin («Legal regime of artificial intelligence technologies used in telemedicine», 2021), A.P. Ivanova («Legal problems of using artificial intelligence in healthcare», 2021), A.Y. Kiseleva («Application of Artificial Intelligence in Healthcare: Aspects of Medical Law», 2020), S.A. Privalov («Artificial Intelligence Technologies in Ensuring the Right to Health Protection, Accessible and Quality Medical Care: Prospects and Problems of Regulation», 2021), N.Y. Chelysheva («Features of Legal Regulation of the Application of Digital Technologies in Healthcare as a Guarantee of Ensuring the Proper Quality of Medical Services», 2021), E.E. Chernykh («Digital Medicine: Risks of Legal Implementation of Innovations in Healthcare», 2020).

Works related to the study of the general legal regime of AI are often found in Russian and foreign scientific literature. Significant contribution to the study of this issue was made by the following Russian researchers: V.V. Arkhipov and V.B. Naumov («On Some Issues of Theoretical Basis for the Development of Robotics Legislation: Aspects of Will and Legal Personality», 2017), S.V. Bakhin («To the Question of Legal Personality of Artificial Intelligence», 2022), A.A. Vasiliev and D. Shpopper («Artificial Intelligence: Legal Aspects», 2018), A.V. Gabov («Legal Personality: Traditional Category of Law in the Modern Era», 2018), V.A. Laptev («The concept of artificial intelligence and legal responsibility for its work», 2019), A.V. Malyshkin («Integration of artificial intelligence into public life: some ethical and legal problems», 2019), I.V. Ponkin and A.I. Redkina («Artificial intelligence from the point of view of law», 2018), I.A. Filipova («Legal regulation of artificial intelligence: regulation in Russia, foreign research and practice», 2018) and others. The works of these authors offer approaches to solving the problems of legal personality and responsibility of artificial intelligence, the definition of its concept, etc.

Among foreign scholars, the following studies are of great importance: S.M. Omohundro («The Basic AI Drives», 2008), L.B. Solum («Legal Personhood for Artificial Intelligences», 1992), P.M. Asaro («Robots and Responsibility from a Legal Perspective», 2007), S. Beck («Intelligent Agents and Criminal Law – Negligence, Diffusion of Liability and Electronic Personhood», 2016), S. Deva («Can Robots have Human Rights Obligations? A Futuristic Exploration», 2012), H. Eidenmueller («The Rise

of Robots and the Law of Humans», 2017), S.M. Solaiman («Legal personality of robots, corporations, idols and chimpanzees: a quest for legitimacy», 2017), L. Wein («The Responsibility of Intelligent Artifacts: Toward an Automation Jurisprudence», 1992) and other authors, who have attempted a comprehensive philosophical and legal analysis of the nature of the AI.

At the same time, legal studies devoted to the regulation of AI practically do not touch upon the problems of the relationship between international law and STP. The principles and objective regularities of AI work, which can be the basis for special legal regulation, also remain unattended. The overwhelming majority of works are aimed at accumulating and critically evaluating already existing legal concepts, their authors limit themselves to analyzing the legal doctrine or legal and technical properties of the currently few sources of law in the field under consideration.

The subject of the research is the relations (including cross-border) in the field of development, production, admission into civil turnover, distribution and use of artificial intelligence systems for medical purposes, as well as the international legal regime of regulation of such relations.

The object of the research is the international legal regulation of the use of artificial intelligence for medical purposes.

The purpose of the research is to determine the main provisions of special international legal regulation of relations related to the creation and use of artificial intelligence systems in the field of medicine.

The mentioned goal is concretized in the following **tasks of the research**, which the author sets for himself:

1. to investigate the legal regulation of STP, its interrelation with international law, as well as to identify the main factors that influence the content of international legal norms aimed at regulating scientific achievements and technical discoveries;

2. to reveal the content of forms of international cooperation, as well as to determine the main directions of unification of international legal regulation of the use of artificial intelligence in medicine;

3. to investigate the international legal framework for ensuring the safety of human health intervention and to derive principles for the use of scientific and technological advances (including AI) in health care;

4. generalize special international legal principles of regulation of intelligent systems, taking into account the specificity of AI regardless of the sphere of application;

5. to investigate the main directions of ensuring the safety of the use of AI systems in medicine by improving the protection of personal data, control over the circulation of medical devices and the procedure for obtaining informed consent for medical intervention;

6. determine the peculiarities of tort liability for harm caused by AI in the provision of medical care and formulate an approach to solving the problem of liability.

Methodology of the research. The work is based on the systematic method, which made it possible to carry out an interdisciplinary study of the nature of AI and forms of its application in medicine, taking into account a comprehensive assessment of socio-economic, ethical and legal factors of universal (worldwide) importance, in particular, the specifics of international legal regulation of STP results.

The following set of general scientific methods was used in the study:

— analysis and synthesis, which were actively applied to solve the research tasks related to the study of multiple existing approaches and the creation of author's concepts for solving the problems under consideration;

— induction, the application of which is necessary to study the interaction between law and scientific and technological progress, as well as to assess the current fragmented international legal regulation of relations related to the use of AI;

— deduction, an example of which is the study of legal institutions and doctrinal concepts from the position of their compliance with the objective regularities of the functioning of AI and law, as well as the relationship between international law and STP;

— analogy, the use of which is necessary to fill gaps in international legal regulation;

— modeling, which manifested itself in the study of forms of international cooperation in the field of AI;

— abstraction, the application of which allowed an objective assessment of legal norms and categories in their autonomous understanding.

Due to the legal nature of the research, formal-legal, hermeneutical and comparative-legal methods were also applied.

Theoretical basis of the research. The works of Y.V. Blokhina, M.S. Varyushin, A.P. Ivanova, A.Yu. Kiseleva, S.A. Privalov, I.M. Rassolov, N.Y. Chelysheva, E.E. Chernykh, S.G. Chubukova, T.N. Erivantseva, etc., devoted to general legal problems related to the use of AI in medicine, were of particular importance in this study.

The thesis used the works of foreign authors on the legal problems of the use of artificial intelligence in cross-border relations, including in the field of health care, among which we can mention the studies of P.M. Asaro, S. Beck, J.M. Balkin, L. Wein, A. Willems, S. Deva, T. Davenport, A. Keisner, R. Kalakota, S.M. Omohundro, L.B. Solum, J. Harris, H. Eidenmueller and others.

Since the present study is primarily devoted to international legal regulation, we used works on the general theory of international law, especially in the field of the relationship between international law and STP, the authors of which are L.A. Afanasyeva, S.V. Bakhin, L.N. Galenskaya, A.V. Zazhigalkin, M.I. Lazarev, S.A. Malinin, M.K. Suleimenov, V.P. Talimonchik, O.N. Tolochko, S.V. Chernichenko. Considering the issues of the general theory of law, the author referred to the works of D.A. Azarevich, S.S. Alekseev, S.I. Arkhipov, V.V. Lazarev, M.N. Marchenko, A.V. Mitskevich,

P.I. Stuchka, A.F. Cherdantsev, L.S. Yavich. In the study of international legal bases of ensuring the security of intervention into the sphere of human health the works of D.G. Bartenev, D.I. Bogdanova, A.I. Ioyrysh, V.S. Mikhailov were used.

Special attention was paid to the works devoted to legal institutions and principles of artificial intelligence regulation, namely, the studies of V.V. Arkhipov, P.P. Baranov, S.V. Bakhin, A.A. Vasiliev, A.V. Gabov, G.A. Gadzhiev, N.A. Dmitrik, V.A. Laptev, I.N. Mosechkin, V.B. Naumov, A.V. Malyshkin, I.V. Ponkin, A.I. Redkina, O.N. Tolochko, F.V. Uzhov, I.A. Khavanova, D. Shpopper, and others.

The works of Ch. Antoniades, A. Kendall, J. McCarthy, J.T. Senders, J. Thrall, F. Jiang, D.S. Chara, T. Ching, J. Huang, and others have been studied to analyze the technical features of the algorithms.

Of great importance are the studies of medical topics related to the peculiarities of the use of artificial intelligence in the provision of medical care, belonging to D.N. Borisov, A.V. Gusev, A.A. Ivshin, O.Y. Kolesnichenko, A.P. Latkina, A.A. Meldo, T.N. Trofimova, L.V. Utkin, V.M. Fersht, and others.

Regulatory and information basis of the research. The provisions and conclusions stated in the dissertation are based on the analysis of normative acts regulating the legal regime of STP in general and artificial intelligence in particular, as well as the regulation of relations in the field of medicine, among which are the following:

— sources of international law, mainly international treaties (UN, WIPO, WTO, Council of Europe[12]);

— sources of integration law (EAEU, EU);

— sources of national legislation, including Russian (federal legislation, socio-economic planning documents) and foreign law[13];

— international normative documents (declarations, resolutions, recommendations, guidelines, reports, etc.) of a non-binding nature (UNESCO, WHO, ITU, OECD, EU);

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[12] Please note that since 16.03.2022 in connection with the termination of the membership of the Russian Federation in the Council of Europe, the international treaties of this organization have ceased to apply to the Russian Federation, and the decisions of interstate bodies of the Council of Europe are not subject to execution in the Russian Federation on the basis of Article 79 of the Constitution of the Russian Federation. See more: On the termination of international treaties of the Council of Europe with respect to the Russian Federation : Federal Law of 28.02.2023 № 43-FZ // CL RF. 2023. № 10. Art. 1566 ; Statement of the Ministry of Foreign Affairs of Russia on the launch of the procedure of withdrawal from the Council of Europe [Electronic resource] // MID.RU: official website of the Ministry of Foreign Affairs of the Russian Federation. 2022. March 15. URL: https://mid.ru/ru/foreign_policy/news/1804379/ (date of access: 01.09.2023).

[13] In some cases, this study refers to legal acts of the states (USA, UK, EU member states), which at the time of writing are included in the List of foreign states and territories committing hostile acts against the Russian Federation, Russian legal entities and individuals. Please note that in the text of this paper these references are used for informational or comparative legal purposes. See more: On Approval of the list of foreign states and territories committing hostile acts against the Russian Federation, Russian legal entities and individuals : Order of the Government of the Russian Federation of 05.03.2022 № 430-r, ed. of 29.10.2022 // CL RF. 2022. № 11. Art. 1748.

— international standards, technical regulations and other acts in the field of standardization adopted by non-state international (WMA, CIOMS, ISO, IMDRF) and national (IEEE, NEMA) organizations;

— national standards for the use of medical AI.

Internet resources, including electronic editions, news resources, reference-legal systems and blogs of subject matter experts on medical and IT Internet resources were used in writing the paper.

Provisions made for the defense:

1. This study has shown that the use of AI in medicine, biology and pharmacology requires special international legal regulation to ensure the development and implementation of safe technologies in medical practice. It is necessary to start international standard-setting at the present time, because further inaction will lead to the aggravation of the technological gap between developed and developing countries, impossibility of convergence of national legal orders, incompatibility of technical solutions developed in different states and treatment methods associated with the use of innovations. Clear international legal provisions in this area will prevent unscrupulous actors in international relations from using dual-use AI technologies for illegal and inhumane purposes, abusing the scientific potential of medicine.

2. The subject of international legal regulation of the use of AI in the field of medicine should be relations related to the development, admission to use, production, introduction into civil circulation, transportation, storage, sale, operation, maintenance and decommissioning of AI systems; relations of transboundary exchange of intellectual technologies, methods and data; relations to ensure the safety of the use of AI in the provision of medical care and data processing. At the same time, it is impossible to unambiguously define in advance the range of issues to be regulated due to the constant development of intellectual technologies. Therefore, the regulation of the use of AI technologies in healthcare will be carried out in several stages. This or that technology can be put into circulation only after the legal problems caused by its use have been identified.

3. Regulation of the use of AI systems in medicine can be carried out at both national and international levels. Establishment of common international legal regulators can ensure interoperability of technical parameters, unification of requirements for AI safety, measures to minimize the risk of using dual-use technology to cause damage to the national interests of states, human rights and freedoms, as well as cross-border exchange of medical technologies and the results of their implementation in medicine, biology and pharmacology between countries that are ready to establish mutual obligations in this area. Priority directions of international cooperation are: creation of a system of international standards in the field of development, introduction into civil circulation and operation of controlled and safe intellectual systems; ensuring uniformity of information exchange processes and scaling of databases; reduction of administrative barriers to cross-border use, exchange and protection of the results of intellectual activity.

4. International legal regulation of the use of AI in medicine is part of the system of international law, which determines the applicability to this area of relations of generally recognized principles and norms of international law; international legal principles in special areas – regulation of the achievements of scientific and technological progress, regulation of intervention into the sphere of human health protection, protection of human rights and fundamental freedoms, protection of intellectual property. These international legal norms can be used to eliminate legal conflicts, fill the gaps of special regulation and, in general, act as a criterion for the legality of the use of AI.

5. At the moment, international regulation of certain aspects of AI use in medicine is carried out without any coordination. This work is carried out by international intergovernmental (WHO, UNESCO, ITU, WIPO, WTO) and non-governmental organizations (WMA, CIOMS, ISO, IMDRF, NEMA, IEEE), integration associations, and individual states. This creates the risk of haphazard development of a contradictory set of legal regulations. In order to streamline standard-setting and law enforcement activities in the field of intellectual technologies, it is advisable to form a special body within the UN (similar to the UN Commission on International Trade Law), which would be entrusted with the coordination function.

6. Despite their considerable volume, the norms of the existing international law on health protection, in the field of medicine, biology, pharmacology, etc. have not yet been gathered together into a separate branch of international law, which leads to inefficiency of interstate cooperation and existing international legal mechanisms for the resolution of problems in the field of health care. The formation of an independent branch of international medical law is seriously hindered by the fact that legal norms on medicine and health care are scattered in various branches and institutions of existing international law. In order to create this branch of international law, it will be necessary to adopt a fundamental international treaty regulating the subject matter, principles and specifics of regulation of relations in the sphere of protection of health of people and nations. When developing international legal regulation of relations in the sphere of health protection, we will inevitably encounter difficulties due to the different capabilities of states to ensure an equal level of medical care.

7. International legal regulation of the use of AI in the field of medicine should take into account the peculiarities of specialized medical care, socio-economic consequences of digitalization, technical aspects of AI, legal principles of regulation of the achievements of STP and the legal basis for their use in healthcare, as well as objective regularities of the functioning of law as a regulator of social relations (its internal and external limits). The totality of international legal norms regulating the use of intellectual technologies in medicine is inter-branch, in connection with which it cannot be currently singled out as an independent branch or legal institute of international law, but represents a set of separate legal norms within the framework of already existing international legal institutions.

8. Legal regulation of STP achievements, including AI, should be aimed, on the one hand, at preventing and minimizing the negative consequences of technological development, on the other hand, at creating conditions for further scientific and technological development. The development of unified legal provisions on this issue is complicated by technological inequality and different capabilities of states to introduce scientific and technological achievements into practice. The factor complicating the regulation of the use of achievements of scientific and technological development is the fact that scientific and technological development occurs rapidly, and the law, in most cases, does not have time to reflect the changes occurring in social relations.

9. AI requires the solution of its own unique range of issues that are not relevant in the context of application of other latest technologies (ensuring transparency of decision-making by algorithms, peculiarities of liability for harm caused by AI, etc.). Medical application of intellectual technologies has its own specifics of legal regulation of their use (control over the circulation of AI systems at the post-registration stage, ensuring compatibility of data formats, software and information systems, etc.). Therefore, the involvement of AI in the process of medical intervention implies the need for special legal regulation.

10. Based on the analysis of existing international legal provisions, the author summarizes the principles to which the use of scientific and technological achievements (including AI) in health care should be subject: 1). Responsibility of states for the health of their peoples; 2). Respect for human rights, fundamental freedoms and dignity, including the right to enjoy the highest attainable standard of health; 3). Transition to universal health coverage; 4). Ensuring the safety of interventions into the sphere of human health; 5). Cooperation among States, promoting the free exchange of scientific knowledge and information in the fields of biology, genetics and medicine.

11. As a result of the conducted research, the following special legal principles of regulating relations related to the use of AI were formulated: the principles of transparency, risk management, informed consent and safe use. These principles can be enshrined in the sources of both international and domestic law. In the field of medicine, the priority is to ensure the rights and legitimate interests of the patient, in this regard, special attention should be paid to the safety of the use of artificial intelligence.

12. From the point of view of the theory of law, there are prerequisites for recognizing AI as a subject of law, since algorithms can possess legal will and can also be autonomous, i.e. capable of making final decisions without human intervention. Criticism of this position is based on an anthropocentric understanding of law, which distorts the legal nature of the technology. Artificial intelligence can be recognized as a subject of a special kind (sui generis), the scope of legal personality of which should depend on the field of application and the level of scientific and technological development. In the field of medicine, this approach will make it possible to organize a fully autonomous process of medical care. At the same time, taking into account the level of technological development at the moment, it is

premature to recognize AI as a subject of law. Existing medical AI systems require human control and are objects of rights: computer programs and medical devices.

13. The safety of AI use in medicine is achieved by adapting the procedure for obtaining informed voluntary consent for medical intervention to the conditions of digitalization of healthcare, protecting the confidentiality of personal data (striking a balance between privacy, technology development and protection of public interests), as well as controlling the circulation of medical devices (improving technical and clinical trial procedures, risk forecasting, completeness of the rules of use and continuous technological development). In order to regulate AI technologies, the principle of protection by design should be enshrined, the essence of which is to build into the algorithm program measures and restrictions aimed at preventing harm. The requirements to ensure protection of AI systems against unauthorized access are also an integral part of the concept.

14. Conventional corpus delicti of special torts (causing harm by a source of increased danger or due to defects of goods) do not take into account the specifics of AI (its autonomy) and cannot be applied to relations in the field of healthcare. Professional participants (medical personnel) should be subject to special standards of liability, including the principle of personal responsibility of physicians for decisions made in an automated manner. An effective tort liability mechanism should be based on combining the general tort and the principle of risk management between physician and patient in cases where fault cannot be established or the harm is not wrongful, by way of professional presumption or on the basis of informed consent. Enshrining such a concept of tort liability in the sources of international law would not contradict existing regulation, which indicates that it is inadmissible to shift liability from the individual to the algorithm.

Scientific novelty of the research. Based on the results of interdisciplinary research, the author considered the main regularities underlying the development and use of AI in the field of medicine. The study of the relationship between scientific and technological progress and international law, technical aspects of AI work, as well as the transformation of legal institutions and procedures in connection with the spread of artificial intelligence, allowed the author to outline the author's concept of international legal regulation of the use of AI in the field of medicine, as well as to determine its place in the system of international law.

The study is the first to formulate a set of special international legal principles of AI regulation, based on the study of the peculiarities of international legal regulation of the results of STP, technical features of the technology, socio-economic consequences of its introduction and the specifics of medical care. In addition, the author investigated the legal status of AI and identified the trend towards the transformation of traditional legal categories in the modern digital era.

The thesis identifies ways to address the main issues arising in the field of regulation of intelligent technologies. Considerable attention is paid to legal guarantees of ensuring the safety of the use of

artificial intelligence for medical purposes through the study of the peculiarities of the automated order of clinical decision-making and personal data processing, as well as the improvement of the system of quality assessment of AI systems within the framework of control over the circulation of medical devices.

The dissertation research contains the author's concept of tort liability for harm caused by medical algorithms in the provision of medical care. The presented concept can also be applied to the use of intellectual technologies in other spheres of activity.

The author analyzed the main directions and forms of international legal cooperation in the field of the use of AI for medical purposes. In addition, based on the results of the analysis of existing sources of law and developments in legal doctrine, the author proposed legal instruments that are most suitable for regulation in the field of the use of artificial intelligence for medical purposes at the international level.

Theoretical and practical significance of the research. The provisions and conclusions contained in the thesis can be used in the creation of international regulations that form the basis of the legal regime of the use of AI in medicine, as well as for the development of national legislation that contributes to the cumulative improvement of the quality and accessibility of medical care, cross-border exchange of technologies.

The dissertation research has formed a set of special legal principles and norms that allow to ensure the safe use of artificial intelligence systems in medical practice, as well as compensation for harm. Proper implementation of the provisions formulated in the work into the sources of law will strengthen the protection of human life and health, his basic rights and freedoms, as well as lead to the introduction of controlled and safe intelligent technologies in medical practice.

The study allows adapting traditional legal institutions and categories (subject of law, informed consent, etc.) to the relations related to the use of AI through the identification of objective regularities of functioning of algorithms and international legal regulation of the results of STP. The materials of the work can be used in teaching courses of international public and private law, a special course on the topic of research, as well as in educational and educational-methodological literature.

Approbation of the research results. Approbation of the results of the research took place in the format of its discussion at the Department of International Law of St. Petersburg State University. The main conclusions and provisions of the research are contained in publications, reports and speeches of the author at international and all-Russian scientific-practical conferences: All-Russian scientific conference within the XIV Annual Scientific Session of postgraduates and young scientists (Vologda State University, November 2020), V International Scientific and Practical Conference «Law and Modern Economy: Experience and Future» (St. Petersburg State Economic University, April 2022), XXXV International Scientific and Practical Conference «Law and Modern Economy: Experience and Future»

(St. Petersburg State Economic University, April 2022), XXXV International Scientific and Practical Conference «Law and Modern Economy: Experience and Future» (St. Petersburg State Economic University, April 2022), XXXV International Scientific and Practical Conference «Law and Modern Economy: Experience and Future» (St. Petersburg State University, April 2022).

The results of the study are presented in 5 scientific articles published in leading peer-reviewed journals and editions recommended by Higher certification commission of the Ministry of Education and Science of the Russian Federation, totaling 5,28 p.sh., as well as in 3 scientific articles indexed in RSCI.

The validity and reliability of the main results of the research are confirmed by their approbation through discussion at the Department of International Law of St. Petersburg State University, scientific conferences of various levels, as well as publication in peer-reviewed journals and publications. The conclusions contained in the study are based on a comprehensive analysis of the theoretical, normative-legal and information base on the topic of the thesis with the application of scientific methodology.

The structure of the dissertation is determined by the goals and objectives of the research and consists of a list of abbreviations and symbols, introduction, 4 chapters containing a total of 10 paragraphs, conclusion, list of used sources and 5 appendices.

CHAPTER 1. SCIENTIFIC AND TECHNOLOGICAL PROGRESS AND THE INTERNATIONAL LEGAL FRAMEWORK FOR HUMAN HEALTH INTERVENTION SECURITY

§ 1.1. Scientific and technological progress in health and international law

Certain issues from the sphere of public health and ensuring the security of intrusion into the sphere of human health at different stages of social development have been the subject of special international legal regulation. The first experience of international cooperation in this area is connected with counteraction to the spread of dangerous epidemics (cholera, plague, yellow fever), which showed the objective necessity of cooperation of states in the fight against especially dangerous infectious diseases[14]. The first international agreements on health protection contained quarantine and sanitary norms aimed at preventing and combating the transboundary spread of dangerous diseases.

Thus, in 1851, the first international sanitary conference was held, which was attended by representatives of 12 European states (including Russia). As a result of the conference, in January 1852, a draft of the first international sanitary convention was signed, containing quarantine rules aimed at combating the spread of cholera. At the same time, the 1852 Convention was ratified by only two countries, which showed the difficulty of developing international obligations in this area acceptable to the states. Nevertheless, the 1852 Convention laid the foundations of international legal regulation of health protection[15] and demonstrated the need for sanitary conferences as a form of interaction between states for the next century. The most significant international anti-epidemiological agreement in the first half of the 20th century was the International Sanitary Convention of 1926[16], which codified the norms in the field of epidemic control created since the first international sanitary conferences were held.

International cooperation in the field of health protection was first institutionalized in 1907 with the establishment of the International Bureau of Public Hygiene[17], under the auspices of which subsequent sanitary conferences were held (the International Bureau itself became part of the established WHO in 1946). It is noteworthy that from the beginning of the 20th century the subject of international cooperation in the field of public health began to expand – in addition to the fight against epidemics, international legal acts regulated the issues of treatment of venereal diseases, alcohol and drug addiction (within the framework of conferences held under the auspices of the Health Organization of the League of Nations), labor protection (Convention on Compensation for Workers in Case of Industrial Accidents

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[14] Mikhailov V.S. History of international health law : a monograph / V.S. Mikhailov. Vladivostok: Far Eastern University Publishing House, 1984. P. 12.

[15] Ibid. P. 19.

[16] International Sanitary Convention of 21.06.1926 // CL USSR. 1929. Division II. № 19. Art. 106.

[17] International Agreement concerning the Establishment of the International Public Hygiene Bureau of 09.12.1907 // CL USSR. 1926. Division I. № 69. Art. 529.

1925[18], art. 16 of the Convention concerning Forced Labor in the Field of Health Care 1930[19]) etc. However, international cooperation in these areas until the second half of the XX century rarely led to the creation of international agreements, and the range of issues addressed was extremely narrow.

The situation changed dramatically after the creation of the United Nations, whose Charter[20] for the first time enshrined as one of its goals the promotion and development of respect for human rights and fundamental freedoms. The human right to health protection was first enshrined in Article 25 of the 1948 Universal Declaration of Human Rights[21].

The resolution of international problems in the field of health protection has come to be regarded as one of the conditions of stability and well-being necessary for peaceful and friendly relations between nations based on respect for the principle of equal rights and self-determination of peoples (Art. 57 of the UN Charter). The range of issues related to the protection of health and the development of public health systems brought to the level of interstate cooperation has steadily expanded. At the same time, the problems of ensuring the human right to health and safety in the provision of medical care have become the subject of consideration both within the framework of cooperation for the protection of human rights and cooperation between states in the field of health care.

The Alma-Ata Declaration of 1978[22], issued at the International Conference on Primary Health Care held in 1978, specifically emphasized that the protection and promotion of the health of the people is an essential part of sustained economic and social development. Obviously, the proclaimed objective corresponds exactly to one of the goals of the United Nations as enshrined in its Charter. Accordingly, the achievement of this goal should be realized through international legal instruments.

It is important to note that health issues are directly attributed to the powers of the main UN bodies. Thus, with regard to the competence of the UN General Assembly, Art. 13 of the UN Charter provides that it shall organize studies and make recommendations with a view to promoting international cooperation in the field of health and to assisting in the realization of human rights and fundamental freedoms. With regard to the competence of the Economic and Social Council, Art. 62 of the UN Charter provides that it is authorized to undertake studies and make reports on international health matters.

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[18] ILO Convention № 17 on Workers' Compensation for Industrial Accidents of 10.06.1925 // Conventions and Recommendations adopted by the International Labor Conference, 1919-1956. Vol. I. Geneva: International Labor Office, 1991. P. 101-104.

[19] ILO Convention № 29 concerning forced or compulsory labor of 28.06.1930 // Bulletin of the Supreme Court of the USSR. 1956. № 13. Art. 279.

[20] Charter of the United Nations of 26.06.1945, with amendments and additions of 20.12.1971 // Current International Law. Vol. 1. Moscow: Moscow Independent Institute of International Law, 1996. P. 7-33.

[21] Universal Declaration of Human Rights of 10.12.1948 // Rossiyskaya gazeta. № 67. 05.04.1995.

[22] Alma-Ata Declaration of 12.09.1978 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/declarations/almaata78.shtml (date of access: 30.05.2023).

Within the UN system there is a special specialized agency in this field – the World Health Organization (hereinafter – WHO). The WHO Charter[23] enshrines the principle of responsibility of states for the health of their peoples. However, this wording seems to us to some extent to distort the goals of international cooperation in the field of health care. It should be assumed that every state has obligations in the field of health care not only with regard to its own citizens, but also to people in general. In particular, this implies the inadmissibility of actions that pose a threat to the health of any person, including transboundary activities that may be harmful to human health.

Thus, if we rely on the UN and WHO Charters, we can conclude that instead of the former fragmented approach to solving health problems, in modern international law the protection of the health of individuals and peoples has become an independent area of cooperation.

It is important to note that special provisions regarding the protection of the human right to health were included in such fundamental international treaties as the International Covenants on Human Rights of 1966. Thus, Art. 12 of the International Covenant on Economic, Social and Cultural Rights of 16.12.1966[24] developed the right to health protection, in particular, it enshrined the right of every person to the highest attainable standard of physical and mental health. In order to realize this right, States have obligations to ensure the reduction of stillbirths, to improve all aspects of environmental and occupational health, to prevent and treat diseases, and to create conditions that would ensure medical care and medical assistance to all in the event of illness.

Issues of health protection were also reflected in the International Covenant on Civil and Political Rights of 16.12.1966[25], according to Art. 7 of which a ban on medical or scientific experiments on human beings without their free consent was established. Thus, a set of norms dedicated to the protection of human health began to form in international law. However, special provisions on medicine and health care were not grouped together, but scattered in various branches, sections and institutes of international law.

Gradually, the sphere of regulation of relations in the field of health care began to expand. A significant number of international treaties and normative documents have been concluded regulating the circulation of medicines and narcotic drugs (UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988[26]), the fight against non-communicable diseases (Declaration of

[23] WHO Statutes (Constitution) of 22.07.1946 [Electronic resource] // WHO: [website]. URL: https://apps.who.int/gb/bd/PDF/bd48/basic-documents-48th-edition-ru.pdf?ua=1#page=9 (date of access: 30.05.2023).

[24] International Covenant on Economic, Social and Cultural Rights of 16.12.1966 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/conventions/pactecon.shtml (date of access: 30.05.2023).

[25] International Covenant on Civil and Political Rights of 16.12.1966 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/conventions/pactpol.shtml (date of access: 30.05.2023).

[26] UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 19.12.1988 // Collection of International Treaties of the USSR and the Russian Federation. Vol. XLVII. M., 1994. P. 133.

Commitment on HIV/AIDS of 2001[27]), the development of medical science (CIS Agreement on Cooperation in the Field of Public Health Protection of 1992[28]) etc.: this range of relations is presented in the most general form in Art. 2 of the WHO Constitution and is constantly growing. Sanitary regulation (International Health Regulations of 2005[29]) and labor protection (Convention on Medical Care and Sickness Benefits of 1969[30]) have been further developed.

In addition, special provisions on health protection have been included in international agreements for the protection of certain categories of particularly vulnerable persons: Convention on the Rights of the Child of 1989[31] (Art. 23 and 24), Convention on the Elimination of All Forms of Discrimination against Women of 1979[32] (Art. 11, 12 and 14), Convention on the Rights of Persons with Disabilities of 2006[33] (Art. 16, 22, 25 and 27), Convention on the Health and Medical Care of Seafarers of 1987[34], The International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families of 1990[35] (Art. 25, 28, 43 and 45), the Standard Minimum Rules for the Treatment of Prisoners of 1955[36] (paras. 15, 17, 20, 25, 74 and 78). The protection of health rights in international humanitarian law is specifically regulated for the protection of war victims[37].

At the same time, despite their considerable volume, the norms of the existing international law on health protection, in the field of medicine, biology, pharmacology, etc. have not yet been collected together into a separate branch of international law. This situation prompts some researchers to conduct a comprehensive analysis of the international legal regulation of problems in the field of health care and to single it out as an independent branch of international law[38]. Thus, Prof. V.S. Mikhailov proposed to

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[27] Declaration of Commitment on HIV/AIDS of 27.06.2001 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/declarations/aidsdecl2.shtml (date of access: 30.05.2023).

[28] CIS Agreement on cooperation in the field of public health protection of 26.06.1992 // Bulletin of International Treaties. 1993. № 6. P. 27.

[29] International Health Regulations of 23.05.2005 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/conventions/pdf/health_regulations.pdf (date of access: 30.05.2023).

[30] ILO Convention № 130 on Medical Care and Sickness Benefits of 25.06.1969 // Conventions and Recommendations adopted by the International Labor Conference. 1957-1990. Vol. II. Geneva: International Labor Office, 1991.

[31] UN Convention on the Rights of the Child of 20.11.1989 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/conventions/childcon.shtml (date of access: 30.05.2023).

[32] UN Convention on the Elimination of All Forms of Discrimination against Women of 18.12.1979 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/conventions/cedaw.shtml (date of access: 30.05.2023).

[33] UN Convention on the Rights of Persons with Disabilities of 13.12.2006 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/conventions/disability.shtml (date of access: 30.05.2023).

[34] ILO Convention № 164 on Seafarers' Health and Medical Care of 08.10.1987 // Conventions and Recommendations adopted by the International Labor Conference. 1957-1990. Vol. II. Geneva: International Labor Office, 1991.

[35] UN International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families of 18.12.1990 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/conventions/migrant.shtml (date of access: 30.05.2023).

[36] Standard Minimum Rules for the Treatment of Prisoners of 1955. [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/conventions/prison.shtml (date of access: 30.05.2023).

[37] Bakhin S.V. Scientific and technological progress in the field of medicine and international legal protection of human rights: diss. ... cand. jurid. sciences: 12.00.10 / Bakhin Sergey Vladimirovich. St. Petersburg, 1990. P. 116-125.

[38] See, for example, Bartenev D.G. The right to health protection in international law: diss. .... cand. jurid. sciences: 12.00.10 / Bartenev Dmitry Gennadievich. St. Petersburg, 2006. P. 41-49.

consider the totality of international legal norms on health protection as a separate branch of international law – international health law[39].

This approach, however, has not received support in the science of international law. The question of the division of international law into branches is a matter of much controversy. The problem lies in the fact that international legal science borrows the criteria for the delimitation of branches from the general theory of law, while it derives its generalizations based solely on the specifics of national law. As a rule, two criteria – the subject matter and the method of legal regulation – are used to classify legal norms into branches[40]. However, these criteria do not correlate well with the system of international law, which requires a special approach[41].

The absence of a universally recognized position on this issue in international legal science[42] leads to the existence of multiple points of view on the system-forming criteria for determining the branch of international law. Thus, according to Prof. E.A. Shibaeva, in addition to the subject and method of legal regulation, the system-forming factor of the international legal branch is the volume of normative material and specificity of legal norms[43] (this point of view was also shared by Prof. D.I. Feldman[44]). Prof. A.I. Ioyrysh noted that the formation of a new branch of international law depends to a large extent on the interest and needs of society[45]. As Prof. Y.M. Kolosov points out, a special subject of regulation is sufficient to distinguish a branch of international law[46].

At the same time, as Prof. L.N. Galenskaya notes, the existence of specific social relations, relations of states in relation to any material subject is not enough to recognize the existence of a branch of law. If we assume the opposite, then it will be impossible to list all branches of law at all. Not all homogeneous isolated social relations are a branch of law [47]. A similar point of view was held by Prof. S.A. Malinin. He pointed out: «However, the existence of a homogeneous group of international relations does not mean that this group can constitute the subject of regulation for an independent branch of law. It is also necessary to determine whether this group of relations represents such a degree of qualitative separateness that would require its own special method of legal regulation... It can be safely asserted that

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[39] Mikhailov V.S. Op. cit. P. 4.

[40] Yavich L.S. To the question of the subject and method of legal regulation / L.S. Yavich // Questions of the general theory of Soviet law: a collection of articles. Moscow: Gosurizdat, 1960. P. 60; Suleimenov M. Law as a system : a monograph. Almaty: Law Firm «Zanger», 2011. P. 80-99.

[41] Shibaeva E.A. Law of international organizations as a branch of modern international law / E.A. Shibaeva // Soviet State and Law. 1978. № 1. P. 105; Lukashuk I.I. International legal regulation of international relations : a monograph / I.I. Lukashuk. Moscow: Mezhdunar. relations, 1975. P. 95.

[42] Feldman D.I. System of international law : a monograph / D.I. Feldman. Kazan: Kazan University Publishing House, 1983. P. 43.

[43] Shibaeva E.A. Op. cit. P. 107.

[44] Feldman D.I. Op. cit. P. 47.

[45] Ioyrysh A.I. Atom and law : a monograph / A.I. Ioyrysh. Moscow: International Relations, 1969. P. 26.

[46] Kolosov Y.M. Mass information and international law : a monograph / Y.M. Kolosov. Moscow: International Relations, 1974. P. 152.

[47] Galenskaya L.N. On the concept of international criminal law / L.N. Galenskaya // Soviet Yearbook of International Law, 1969. M.: Nauka, 1970. P. 254, 256.

it is the disregard for the method of legal regulation that is the source of discord in solving the problems of the system of international law and often leads to the arbitrary allocation of branches of law»[48]. However, based on the same premise, L.N. Galenskaya and S.A. Malinin came to different conclusions. Thus, according to L.N. Galenskaya there are two branches in international law – substantive and procedural law, and according to S.A. Malinin – public and private law.

From our point of view, if in international law we proceed from the criteria of an independent subject and method of regulation, it will be rather difficult to distinguish separate branches of international law. If the criterion of the subject of regulation, nevertheless, allows us to distinguish a group of sufficiently isolated homogeneous legal relations, we will not find an independent method of legal regulation. In fact, in relation to international maritime, air, space, diplomatic, consular and some other parts of international law, the method of legal regulation will remain the same. It is likely that a certain specificity of the method of legal regulation can be found in relation to cooperation in the field of human rights, responsibility in international law, international economic law and some other sections of international law. Therefore, the question of differentiating international law into branches remains open, and its solution depends on many objective and subjective factors[49].

There is no universally recognized system of international law[50]. As Prof. S.V. Chernichenko noted, the multivariability of the system of international law is explained, among other things, by the fact that its various branches are partially combined or interpenetrated. The same norms and institutions can be attributed to different branches. Some branches of international law are in the process of formation. «At the same time, – noted S.V. Chernichenko, – there are categories of norms that play an important role in interstate relations, and quite numerous, which have not yet crystallized into clear branches. These include norms regulating scientific and technical cooperation, cooperation in the field of health care, etc. Conventionally, they can be categorized as norms regulating cooperation on special issues»[51]. Regarding the division of international medical law proposed by some authors, S.V. Chernichenko points out that it can be considered a sub-branch within the branch, conditionally called «cooperation on special issues». Noting that such a name is not the most successful, S.V. Chernichenko believed that it could be temporarily used as a reference point.

Many specialists, both in the Russian Federation and abroad, predict that the 21st century will see a rapid development of scientific and technological progress in medicine and health care. Even now, in addition to the artificial intelligence we are specifically considering, such innovations as nanotechnology, robotics, Big Data and many other advanced technologies and achievements are being

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[48] Malinin S.A. Peaceful use of atomic energy : international legal issues / S.A. Malinin. Moscow: International Relations, 1971. P. 6-7.

[49] Feldman D.I. Op. cit. P. 43.

[50] Chernichenko S.V. Contours of international law. General issues: a monograph / S.V. Chernichenko. Moscow: Scientific Book, 2014. P. 67.

[51] Ibid. P. 68.

introduced. Therefore, we agree with S.V. Chernichenko's thesis that the branch of international medical law is currently at the stage of formation, and it is premature to say that such a branch has been formed yet. In all likelihood, there will still be special regulation in international law in relation to health, medicine, biology, pharmacology, etc.

In addition, as noted above, the formation of an independent branch of international medical law will be seriously hindered by the fact that legal norms on medicine and health care are already scattered in various branches and institutions of existing international law. In our opinion, the existing international legal norms on the protection of the health of people and nations do not yet form an integral branch of international law. In the field under consideration there is no system of special legal principles, there are no universal international treaties on medicine and health care, and it is such treaties that, as a rule, lay the foundations of an independent branch. At the moment, only certain issues in the field of medicine, biology and pharmacology, which states have agreed to settle among themselves, have become the subject of special regulation. Therefore, the formation of such a branch as international medical law is currently in need of further discussion.

At the same time, the noted difficulties with the formation of an international legal system of norms on health protection do not contribute to the strengthening of global inter-State cooperation in this area. The spread of the COVID-19 coronavirus pandemic, having become a real test of the effectiveness of cooperation between States in the field of health care, has shown the insufficient level of cooperation between States in this area. Financially and organizationally, the international community was unable to cope with the spread of a dangerous epidemic. Moreover, the question has arisen as to what restrictions (including human rights) can be imposed by States to prevent the spread of the pandemic. In all likelihood, special consideration should be given to the possibility of using coercive medical measures in the interests of public health[52]. Thus, the COVID-19 pandemic has demonstrated the ineffectiveness of existing international legal mechanisms in dealing with such challenges. As experts warn that pandemic situations similar to COVID-19, or even more dangerous cases, cannot be ruled out in the future, it is necessary to return to a comprehensive discussion of the issue of ensuring health cooperation between States at the global level.

Taken together, these factors clearly demonstrate the need to further strengthen inter-State relations, including through the formation of a comprehensive branch of international law on the protection of the health of individuals and peoples in the future. Formalization of international medical law as an independent branch will make it possible to bring together and systematically regulate everything that relates to ensuring the sanitary and epidemiological well-being of man, his life and health. We mean the

[52] In domestic international legal science the issue of international legal regulation of coercive medical measures was raised only once: see Bakhin S.V. Coercive medical measures and human rights / S.V. Bakhin // in the collection: Modern problems of medical law and the right to health protection. Materials of the International Scientific and Practical Conference. Moscow, 2003. P. 33-44.

establishment of interrelation between medical, sanitary, ecological, economic and technological aspects of ensuring medical and biological safety of a human being. Naturally, the establishment of legal standards and clear legal prescriptions in this area is a rather complicated issue. But this does not mean that the prospects for the formation of international medical law should not be thought through and developed today. In particular, on the agenda is the question of cardinal principles on which international medical law should be built in the future.

Consequently, the establishment of the above-mentioned branch of international law will require the adoption of a fundamental international treaty regulating the subject matter, principles and specifics of the regulation of relations in the sphere of protection of the health of people and nations. It is noteworthy that the draft of such a treaty (International Convention on Human Rights in the Field of Medicine) was proposed back in 1990 by Prof. S.V. Bakhin[53]. However, the draft convention, despite the comprehensive and universal nature of its provisions, was not submitted to the interstate level[54]. This circumstance indicates that states are not ready for the appropriate level of cooperation, which has its own objective grounds.

In developing international legal regulation of relations in the sphere of health protection, we will inevitably encounter difficulties due to the different capacities of states to ensure an equal level of their health care. In this regard, in the absence of effective mechanisms to reduce inequality (primarily technological inequality) between developed and developing countries, there will be a high probability of failure to reach agreement on the establishment of detailed and enforceable international commitments in this area.

An integral part of the general strategy of legal regulation in the field of health care is the issue of regulating the use of the latest scientific and technical achievements in the field of medicine, biology and pharmacology. One of the most promising and significant results of STP is AI, under which we understand an artificial computer system that is capable of autonomous thinking activity, i.e. independently perceive, understand and process information, including with the use of algorithms created (modified) by the system itself, make intermediate (procedural) and final decisions not prescribed in advance, learn and self-learn on the basis of experience[55].

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[53] Bakhin S.V. Scientific and technological progress in the field of medicine and international legal protection of human rights: diss. ... candidate of juridical sciences. P. 240-269.

[54] It is noteworthy that the ideas formulated in the draft comprehensive convention proposed by S.V. Bakhin were used in the development of the Council of Europe Convention for the Protection of Human Rights and Dignity in Connection with the Application of Biology and Medicine of 04.04.1997, developed within the framework of the Council of Europe. Nevertheless, the regional character and removal of fundamental normative provisions from the Oviedo Convention of 1997 did not allow this Convention to become a starting point for the beginning of the formation of the branch of international medical law.

[55] The rationale for choosing this author's definition is contained in Appendix C, and it is in this understanding that we use the term «AI» (and its derivatives) in this dissertation study.

Active development of STP and introduction of its achievements into practice remain, for the most part, outside the sphere of international legal regulation, which does not allow to ensure the realization of human rights and freedoms at the appropriate level, as well as exacerbates technological inequality of states. Further technological development, including smart technologies, is generally unpredictable, which may give rise to a multitude of legal problems in the near future, all of which are currently impossible to define (see Appendix B). However, some experts are already warning that the uncontrolled introduction of the latest information technologies, in particular artificial intelligence, may threaten mankind with unfavorable consequences. For example, as we noted earlier, in March 2023, more than a thousand AI and IT industry experts (including I. Musk, S. Wozniak) expressed concerns about the creation of new «advanced» versions of AI because they could pose a serious danger to humanity[56].

Moreover, the achievements of STP (and artificial intelligence in particular) can be used for dual purposes, i.e. both for the benefit and detriment of individuals, states or humanity as a whole. At the same time, increased attention should be paid to the targeted use of scientific discoveries and technical solutions to the detriment of human beings and the security of states. As technological progress in the field of medicine, biology and pharmacology develops, the threat of possible misuse of technological achievements and the extent of their impact on the sphere of human life and health and the health care system of States increases. In this connection, the problems of (1) ensuring the protection of human beings and States from inhuman abuse of the scientific potential of medicine and (2) developing a system of international control over the activities of states that could harm universal values and interests are of particular relevance. International law can provide effective means of ensuring international security and State control over science and technology, while strictly respecting the international legal principles of sovereign equality, non-interference in internal affairs, respect for human rights and freedoms[57] and reciprocity[58]. In order to prevent abuses in the implementation of international obligations in this area, States must retain the ability to ensure their national security and the foundations of the rule of law and morality.

It should be taken into account that the effectiveness of international cooperation (and the fulfillment of international obligations) in this area largely depends on the interest of states in cooperation and good faith fulfillment of international obligations. The choice of counterparties and form of international cooperation is a matter of discretion for each State. An example of the exercise of such sovereign powers

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[56] See: Pause Giant AI Experiments: An Open Letter [Electronic resource]: Open Letter // FUTUREOFLIFE.ORG: official website of Future of Life Institute. [Cambridge], 2023. URL: https://futureoflife.org/open-letter/pause-giant-ai-experiments/ (date of access: 30.05.2023).

[57] Bakhin S.V. Scientific and technical progress in the field of medicine and international legal protection of human rights: diss. ... candidate of juridical sciences. P. 12, 27-32.

[58] Reciprocity is one of the principles of Russia's foreign policy according to paragraphs 18 and 24 of the Concept of Foreign Policy of the Russian Federation.

is the categorization by the Russian Federation of certain foreign states as unfriendly countries due to their unfriendly actions and actions contrary to international law, and the recognition of such subjects of international law as bad faith[59]. For this reason, the conclusions about the need for a universal treaty or the effectiveness of extensive inter-State cooperation reached by the author of the study in no way imply ignoring national interests and diminishing the sovereignty of individual States in order to establish the relevant international legal regulation or cooperation as soon as possible.

Thus, the constructive process of elaboration of special international legal regulation initiated by the Russian Federation in the current geopolitical situation should be started first of all with the states that are not unfriendly in the sense of Russian legislation, which will make it possible to lay the legal basis for future universal regulation. At the same time, in the future, the issue of bringing international cooperation to the universal level must inevitably be raised, since the uncontrolled development of trans-national AI technologies, which can create problems of international scale, can turn into serious threats to the national security of states. In turn, the development of a set of universal international legal norms, ensuring the participation of the largest number of states in universal international treaties (adopted, first of all, under the auspices of the UN), as well as priority attention to the uniform interpretation and application of such treaties is one of the main goals of Russia's foreign policy (paragraphs 22 and 23 of the Concept of Foreign Policy of the Russian Federation).

In this part, we can only reiterate that the cooperation of States (at the regional or universal level) must be based on strict observance of the universally recognized principles and norms of international law in order to ensure international peace and security, which also corresponds to paragraphs 6, 18 and 23 of the Concept of Foreign Policy of the Russian Federation. Moreover, subjects of international law already have effective legal means to protect their interests in case of non-fulfillment of international obligations. Thus, the Vienna Convention on the Law of Treaties of 1969[60] provides for the possibility of suspension or withdrawal of a party from the relevant international treaty, which was used by Russia, for example, when withdrawing from the Council of Europe in March 2022. The Russian Federation has an additional possibility to ensure its national interests in such a case through the application of Article 79 of the Constitution of the Russian Federation.

The latest achievements of STP push us to the activation of international standard-setting and convergence of national legal orders in the field of health protection. L.A. Afanasieva drew attention to the gaps and conflicts caused by the emergence of new or non-regulation of existing social relations

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[59] See: On the application of special economic measures in connection with unfriendly actions of the United States of America and its adherent foreign states and international organizations : Decree of the President of the Russian Federation of 28.02.2022 № 79, ed. of 09.06.2022, as amended on 09.08.2023 // CL RF. 2022. № 10. Art. 1465; On Approval of the list of foreign states and territories committing hostile acts against the Russian Federation, Russian legal entities and individuals : Order of the Government of the Russian Federation of 05.03.2022 № 430-r, ed. of 29.10.2022 // CL RF. 2022. № 11. Art. 1748.

[60] Vienna Convention on the Law of Treaties of 23.05.1969 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/conventions/law_treaties.shtml (date of access: 01.09.2023).

formed under the technological development and use of its results. In her opinion, the increasing complexity of social relations in connection with the development of technology, the emergence of new and transformation of existing activities naturally leads to the need for their legalization and the growing role of international law (both private and public)[61].

New technologies (robotics, AI, nano-, biotechnology, etc.) provide completely new opportunities for the provision of timely, quality and affordable medical care (primary, specialized, emergency and palliative care). However, the incompatibility of technical parameters, information-exchange processes, safety requirements and the different procedure for utilizing the achievements of STP may make it difficult or even impossible to use technologies in cross-border relations, as well as the exchange of health products and health services in international trade.

In addition, uncoordinated norm-setting by states, interstate entities and non-governmental organizations on the regulation of the use of AI can hinder the development and introduction of safe technologies into medical practice, which also necessitates the development of a unified international legal regulation. Moreover, it is necessary to start international standard-setting at the present time, as further inaction will lead to the aggravation of the technological gap between developed and developing countries, the impossibility of convergence of national legal orders, incompatibility of technical solutions developed in different countries and treatment methods related to the use of innovations, which will also prevent unscrupulous actors in international relations from using dual-use AI technologies to the detriment of other states or to jeopardize human rights and freedoms[62].

Particular attention should be paid to AI, which is a highly effective tool that can significantly increase health coverage and quality (see Appendix A for more details on all the benefits of AI systems in medicine). Artificial intelligence, as a scientific and technological achievement closely linked to information and communication technologies, is becoming part of a fundamental transformational shift resulting in the emergence of a global information society[63]. As noted in UNGA Resolution № A/RES/70/1 of 21.10.2015 «Transforming our World: The 2030 Agenda for Sustainable Development»[64], the spread of information and communication technologies offers enormous opportunities to accelerate human progress and bridge the digital divide and build a knowledge-based society.

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[61] Afanasyeva L.A. Scientific and technological progress and the expansion of the scope of private international law / L.A. Afanasyeva // Private International Law: Contemporary Problems / Ed. by M.M. Boguslavsky. Moscow: Theis, 1993. P. 428.

[62] Nikitenko S.V. International legal regulation of the use of artificial intelligence in the field of medicine / S.V. Nikitenko // Herald of V.N. Tatishchev Volga University. 2023. Vol. 1. № 3 (105). P. 216-217.

[63] Talimonchik V.P. Concept of global information society / V.P. Talimonchik // International public and private law: problems and prospects. Liber amicorum in honor of Professor L.N. Galenskaya / ed. by S.V. Bakhin. SPb.: SPbU Publishing House, 2007. P. 157-174.

[64] Transforming our World: The 2030 Agenda for Sustainable Development: Resolution adopted by the UNGA on 21.10.2015 № A/RES/70/1 [Electronic resource] // UNCTAD: [website]. URL: https://unctad.org/system/files/official-document/ares70d1_ru.pdf (date of access: 30.05.2023).

Consequently, intellectual technologies are transboundary in nature[65], therefore, the most effective and preferable instrument of legal regulation of relations complicated by AI is international law[66].

At the same time, the international legal regulation of issues in the field of health protection is inconsistent: we can find a lot of normative acts regulating separate relations without forming an integral system (branch). In this regard, as noted above, there is a need to develop a universal normative framework, which will allow timely and effective response to new challenges and anticipate the emergence of new problems caused by the constant development of social relations and scientific and technological progress.

The sporadic nature of international legal regulation of health care is also evident in such an issue as the use of the achievements of science and technology in intervening in the field of human health. For example, the need to regulate medical experimentation on human beings was first recognized when the «doctors' case» was considered by the U.S. First Military Tribunal at Nuremberg (U.S. v. Carl Brandt and others)[67]. The rules for human experimentation developed by the Tribunal were given the conventional name of the Nuremberg Code. It is a set of provisions regulating when human experimentation is possible, under what conditions, and how human safety must be ensured. The provisions of the Nuremberg Code were subsequently confirmed and developed in many international legal documents, including the International Covenant on Civil and Political Rights of 1966 (Art. 7), as well as the Additional Protocol of 25.01.2005 (CETS № 195)[68] to the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 04.04.1997[69] (hereinafter – the Oviedo Convention of 1997)[70].

It is noteworthy that STP is associated with law mainly in terms of regulating the consequences of the introduction of its achievements in practice, while scientific research itself rarely becomes the

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[65] Shamlikashvili T.A. Integration of artificial intelligence in the life of society: problems and opportunities / T.A. Shamlikashvili, S.V. Kharitonov // Global Scientific Potential. 2019. № 7(100). P. 51.

[66] Nikitenko S.V. International legal regulation of artificial intelligence: analysis of the current state and prospects of development / S.V. Nikitenko // Herald of V.N. Tatishchev Volga University. 2021. Vol. 1. № 2 (98). P. 153.

[67] Mikhailova A. Historical process: the «doctors' case» at the Nuremberg Military Tribunal / A. Mikhailova // PRAVO.RU: online news edition. URL: https://pravo.ru/story/213678/ (date of access: 30.05.2023).

[68] Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research of 25.01.2005, CETS № 195 [Electronic resource] // Council of Europe: [website]. URL: https://rm.coe.int/168008371a (date of access: 30.05.2023).

[69] Convention of the Council of Europe for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention) of 04.04.1997, ETS № 164 [Electronic resource] // Council of Europe: [website]. URL: https://rm.coe.int/168007cf98 (date of access: 30.05.2023).

[70] Please note that in this dissertation research the references to the normative documents of the Council of Europe are indicated taking into account the termination of the membership of the Russian Federation in the Council of Europe. In this regard, the normative documents of this organization and decisions of its bodies (in accordance with Article 79 of the Constitution of the Russian Federation) have only informational or comparative legal value in this work. It should be emphasized that the Russian Federation has not acceded to the 1997 Oviedo Convention, which is not least due to serious flaws in its structure and content (for more details see pp. 25, 36, 75).

subject of legal regulation, which is pointed out by Prof. S.V. Bakhin[71]. Developments in AI are no exception: the main provisions dedicated to the creation of safe algorithms are contained in the Asilomar Principles of AI adopted by the 2017 Conference on Useful Artificial Intelligence, held in 2017[72]. The document itself and the provisions included in it are ethical rather than legal. However, the Asilomar Principles on AI could be a starting point for the development of relevant regulations.

In the use of AI for medical purposes, as in many other areas related to the human rights implications of STP, ethical and legal standards are closely intertwined. Quite often society evaluates certain scientific and technological achievements and their application to human beings from the point of view of ethics, and only then – from the angle of law. It is not uncommon for rules initially established as ethical to be transformed into legal rules. A similar situation is currently taking place with regard to artificial intelligence.

The expansion of the range of international relations related to health protection, caused by the development of STP[73], has led to the need to regulate the use of biotechnology (cloning, genetic engineering) and new medical technologies (including information technologies). This is reflected in WHO Special Resolution WHA60.29 of 23.05.2007[74]. It should be borne in mind, however, that WHO has previously explicitly stated that it can only provide a checklist of situations where « interventions, coercion or restrictions imposed on people for preventive therapeutic purposes or to advance knowledge about health and disease are relevant to the rights of the individual»[75]. At the same time, WHO has indicated that it is «not appropriate for it to attempt to formulate any specific philosophy on human rights»[76].

This position of WHO inevitably raises the question of how international medical law will be formed. To date, the relevant issues are the subject of consideration of many international interstate and non-state international organizations, with the latter clearly prevailing in this list. For example, the World Medical Association (hereinafter – WMA) has adopted a number of resolutions on medical and medical ethics, humane use of biomedical achievements[77], including the use of intelligent technologies in

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[71] Bakhin S.V. Impact of new technologies on modern international private law (Chapter 5) // Modern Private International Law in Russia and the European Union. Book one: monograph / ed. by M.M. Boguslavsky, A.G. Lisitsyn-Svetlanov, A. Trunk. Moscow: Norma, 2013. P. 106-138.

[72] Principles of working with AI [Electronic resource]: published from the Conference on Useful Artificial Intelligence 11.08.2017 // Future of Life Institute [website]. URL: https://futureoflife.org/open-letter/ai-principles-russian/ (date of access: 30.05.2023).

[73] Ioyrysh A.I. Op. cit.

[74] Medical technologies: WHO resolution from 23.05.2007 № WHA60.29 [Electronic resource] // WHO: [website]. URL: https://apps.who.int/iris/rest/bitstreams/22008/retrieve (date of access: 30.05.2023).

[75] Health aspects of human rights with special reference to developments in biology and medicine. Geneva: World Health Organization, 1976. P. 7.

[76] Fifty-fifth session of WHO. Geneva, January 20-31. 1975. [Text]. Geneva: WHO, 1975. P. 299.

[77] See more: Bakhin S.V. Scientific and technological progress in the field of medicine and international legal protection of human rights: diss. ... cand. juris. sciences. P. 86.

medical care (e.g., WMA Statement on Augmented Intelligence in Medical Care of 2019[78]). Within the Council for International Organizations of Medical Sciences (hereinafter – CIOMS), the use of artificial intelligence in pharmacology is being considered separately, for which a special Working Group XIV on AI in pharmacovigilance has been established[79]. International Medical Device Regulators Forum (hereinafter – IMDRF) is engaged in harmonization of standards related to the circulation of medical devices (admission to civil circulation, quality control, etc.), including intelligent systems. For this purpose, a separate working group on «Medical AI Devices»[80], was set up which, based on the results of its work, adopted the technical regulation «Machine Learning Enabled Medical Devices: Key Terms and Definitions»[81].

At the level of intergovernmental organizations, the use of STP advances in human health interventions has been addressed in the framework of UNESCO (e.g. UNESCO Recommendation on the Ethical Aspects of AI, 2021[82]), the World Telecommunication Union (in particular, Focus Group documents № FG-AI4H «AI for Health», which address terminology, ethical foundations and a number of issues of practical application of AI technologies in certain spheres of medical activity[83]), the World Trade Organization (for example, the Agreement on the Application of Sanitary and Phytosanitary Measures of 15.04.1994[84], the Agreement on Technical Barriers to Trade of 15.04.1994[85] and the Agreement on Trade-Related Aspects of Intellectual Property Rights of 15.04.1994[86]) and WIPO (in particular, the Draft Concept Paper on Issues Related to Intellectual Property and AI Policies[87]). WIPO also initiates

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[78] WMA Statement on augmented intelligence in medical care: adopted by the 70th WMA General Assembly, Tbilisi, Georgia, October 2019 [Electronic resource] // WMA: [website]. URL: https://www.wma.net/policies-post/wma-statement-on-augmented-intelligence-in-medical-care/ (date of access: 30.05.2023).

[79] Working Group XIV Artificial Intelligence in Pharmacovigilance [Electronic resource] // CIOMS: [website] / CIOMS. Geneva, 2023. URL: https://cioms.ch/working_groups/working-group-xiv-artificial-intelligence-in-pharmacovigilance/ (date of access: 30.05.2023).

[80] Artificial Intelligence Medical Devices [Electronic resource]: IMDRF Working group // IMDRF: [website] / IMDRF. [2023]. URL: https://www.imdrf.org/working-groups/artificial-intelligence-medical-devices (date of access: 30.05.2023).

[81] Machine Learning-enabled Medical Devices: Key Terms and Definitions: Technical document, IMDRF/AIMD WG/N67 [Electronic resource] // IMDRF: [website] / IMDRF Working group on Artificial Intelligence Medical Devices. 2022. URL: https://www.imdrf.org/documents/machine-learning-enabled-medical-devices-key-terms-and-definitions (date of access: 30.05.2023).

[82] UNESCO Recommendation on the Ethical Aspects of Artificial Intelligence of 24.11.2021 № SHS/BIO/REC-AIETHICS/2021 [Electronic resource] // UNESCO: [website]. 2021. URL: https://unesdoc.unesco.org/ark:/48223/pf0000380455_rus (date of access: 30.05.2023).

[83] Artificial Intelligence for Health: Focus Group № FG-AI4H of ITU Telecommunication Standardization Sector [Electronic resource] // ITU: [website] / ITU-T SG16: Multimedia and related digital technologies. Geneva, 2018. URL: https://www.itu.int/en/ITU-T/focusgroups/ai4h/Pages/default.aspx (date of access: 30.05.2023).

[84] WTO Agreement on the Application of Sanitary and Phytosanitary Measures of 15.04.1994 // CL RF. 2012. № 37 (Annex, Part V). P. 2075-2088.

[85] WTO Agreement on Technical Barriers to Trade of 15.04.1994 // CL RF. 2012. № 37 (Annex, Part V). P. 2137-2158.

[86] WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 15.04.1994, as amended on 06.12.2005 // CL RF. 2012. № 37. P. 2818-2849.

[87] Draft Concept Paper on Issues Related to Intellectual Property and AI Policies: Prepared by the WIPO Secretariat, published on 13.12.2019, WIPO/IP/AI/2/GE/20 [Electronic resource] // WIPO: [website]. URL: https://www.wipo.int/meetings/ru/doc_details.jsp?doc_id=470053 (date of access: 30.05.2023).

a Discussion on Intellectual Property and AI[88]. Some aspects of the protection of human rights and freedoms during the introduction of the latest technological achievements are addressed by the convention bodies for the protection of human rights. Thus, the Committee on the Elimination of Racial Discrimination, in General Recommendation № 36 (2020) on preventing and combating racial profiling by law enforcement officers, dated 24.11.2020[89], noted that the increasing use of new technologies, including AI, may exacerbate racial discrimination due to the real risk of algorithmic bias[90] (paras. 12, 31)[91].

Thus, to date, more than ten international organizations have addressed the regulation of the use of AI in the field of medicine. At the same time, there is actually no coordination between them, and there is no single center that would concentrate the consideration of all issues related to the biomedical impact on humans. At the same time, it is quite clear that no meaningful results will be achieved without such coordination (this issue is discussed in more detail in § 4.3 of this dissertation).

The dual nature of technological achievements, which can be used both for the benefit and detriment of human beings, and their transboundary nature have made it necessary to regulate the relevant relations by the norms of international law and international normative documents, examples of which are: Universal Declaration on the Human Genome and Human Rights of 1997[92], Additional Protocol to the Oviedo Convention of 1997 of 28.11.2008 (CETS № 203)[93], Agreement on the International System of Cooperation in the field of kidney transplantation «Intertransplant» of 1980[94] and others. Nevertheless, the attempts made to regulate new technologies have not formed a coherent system of norms concerning the regulation of the use of STP achievements in the sphere of human health intervention.

However, this does not mean that there are no provisions in existing international law defining the general legal regime for the use of technological achievements and scientific discoveries at all. Thus, the problems of using the achievements of STP for the first time became the subject of special consideration in 1968 at the International Conference on Human Rights in Tehran. As a result of the discussion,

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[88] WIPO Discussion on Intellectual Property and Artificial Intelligence [Electronic resource] // WIPO: [website] / WIPO. [Geneva, 2019]. URL: https://www.wipo.int/about-ip/ru/artificial_intelligence/conversation.html (date of access: 30.05.2023).

[89] General Recommendation № 36 (2020) on preventing and combating racial profiling by law enforcement officials: adopted by the Committee on the Elimination of Racial Discrimination on 24.11.2020, CERD/C/GC/36 [Electronic resource] // UN Treaty Body Database: [website] / Office of the United Nations High Commissioner for Human Rights. URL: https://tbinternet.ohchr.org/_layouts/15/treatybodyexternal/TBSearch.aspx?Lang=en&TreatyID=6&DocTypeID=11 (date of access: 30.05.2023).

[90] Algorithmic bias refers to an algorithm making unfair, discriminatory, and biased decisions in violation of the function and purpose of the program.

[91] For additional examples of regulation of AI-technologies at the interstate level, see: Nikitenko S.V. International Legal Regulation of Artificial Intelligence: Analysis of Current Status and Prospects for Development. P. 156.

[92] Universal Declaration on the Human Genome and Human Rights of 11.11.1997 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/declarations/human_genome.shtml (date of access: 30.05.2023).

[93] Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes of 28.11.2008, CETS № 203 [Electronic resource] // Council of Europe: [website]. URL: https://rm.coe.int/1680084824 (date of access: 30.05.2023).

[94] Agreement on the international system of cooperation in the field of kidney transplantation «Intertransplant» of 11.12.1980 // Collection of international treaties of the USSR. 1982. Vol. XXXVI. P. 313-318.

a document was adopted on 13.05.1968, which was called the «Proclamation of the Tehran Conference»[95]. This document is conceptual in nature and reflects some fundamental approaches to the protection of human rights. However, the document specifically addresses the relationship between STP and human rights. In particular, it declares: «While recent scientific discoveries and technological developments offer great prospects for social, economic and cultural progress, they may nevertheless jeopardize the enjoyment of rights and freedoms and will therefore require constant attention» (para. 18).

Realizing this task, on 19.12.1968 the UNGA adopted Resolution № A/RES/2450 (XXIII) «Human Rights and Scientific and Technological Progress»[96], which laid the foundation for regulating the results of scientific and technological progress in order to ensure the safety of their use. However, Resolution № A/RES/2450 (XXIII) drew attention to the fact that discoveries themselves could not be positive or negative from a moral point of view, since it was the manner in which they were utilized that was the primary factor[97]. Legal regulation of the use of certain scientific and technological achievements, from our point of view, is possible only after the ways and purposes of their application receive a moral and ethical assessment on the part of society. Without this legal regulation there cannot be. At the same time, it is quite obvious that legal regulation of STP should be aimed, on the one hand, at preventing and minimizing the negative consequences of technological development, on the other hand, at creating conditions for further development of STP, which generally follows from the functions of law as a regulator of social relations[98].

Seven years later, in 1975, the only to date international normative document specifically devoted to the basis of regulation of scientific and technological progress – the Declaration on the Use of Scientific and Technological Progress for Peace and for the Benefit of Mankind of 10.11.1975 (hereinafter – the 1975 Declaration) was adopted[99]. The provisions of the 1975 Declaration are of such a fundamental and generalizing nature that it is legitimate to qualify them as international legal principles of regulation of STP. These cardinal provisions include the following: preventing the use of the results of STP to the detriment of human rights and fundamental freedoms, international peace and security; utilizing scientific and technological discoveries for the benefit of humankind for the economic and social development of peoples and for ensuring human rights and freedoms; non-discrimination, as well as ensuring equal access of all segments of the population to the benefits of science and technology; international

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[95] Proclamation of the Tehran Conference of 13.05.1968 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/declarations/st_hr1_57.shtml (date of access: 30.05.2023).

[96] Human Rights and Scientific and Technological Progress: UNGA Resolution № A/RES/2450 (XXIII) of 19.12.1968 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/ga/23/docs/23res.shtml (date of access: 30.05.2023).

[97] Bakhin S.V. Influence of new technologies on modern international private law. P. 106-138.

[98] Yavich L.S. Problems of legal regulation of Soviet social relations / L.S. Yavich. Moscow: Gosurizdat, 1961. P. 27-28.

[99] Declaration on the Use of Scientific and Technological Progress for Peace and for the Benefit of Mankind of 10.11.1975 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/declarations/science.shtml (date of access: 30.05.2023).

cooperation to utilize the results of STP for the benefit of humankind, respect for human rights and fundamental freedoms, and the protection of human rights and freedoms.

It was planned that detailed international legal norms would be developed on the basis of the 1975 Declaration, for which a special convention was to be adopted. Despite the obvious expediency and justification for the adoption of such an international treaty, a legal act enshrining the international obligations of States in the field of utilization of the results of STP has not been adopted, which is due to the complexity of the issue of the necessary level of protection that could be provided by different States. The development of uniform regulations on this issue is complicated by technological inequalities and the varying capacities of States to put science and technology into practice. The factor complicating the regulation of the use of achievements of STP is the fact that scientific and technological development occurs rapidly, and the law, in most cases, does not have time to reflect the changes occurring in social relations.

Thus, from our point of view, the creation of a universal international legal instrument containing binding provisions for states in the field of health protection in the use of technological advances is still in prospect. In addition, upon closer examination, we will see that each medical technology raises a different set of issues and requires separate regulation. Thus, the regulation of surrogate motherhood is connected with the solution of fundamental issues from the sphere of family law; in the case of transplantation, the problems of ex vivo and ex morte organ removal and ensuring their compatibility with the recipient's organism are brought to the forefront, etc. In a logical way, AI requires solving its own unique range of issues that are not relevant in the context of other technologies (ensuring transparency of decision-making by algorithms, specifics of liability for harm caused by AI systems, etc.). In addition, medical application of intellectual technologies also has specifics in terms of regulation of their use (exercising control over the circulation of AI systems at the post-registration stage, ensuring compatibility of data formats, software and information systems, etc.). Due to the ever-increasing degree of involvement of algorithms directly in the medical intervention process, the issue of ensuring the safe use of AI is acute[100].

However, in our opinion, the specificity of the use of various technologies does not prevent the formation of general international legal regulation, laying the legal foundations for the use of the achievements of STP, since the considered area of social relations has a number of general regularities.

However, it should not be assumed that the regulation of the use of science and technology will have to be started from scratch. The current international law has a number of cardinal provisions that undoubtedly apply to all spheres of social life. It is about the basic principles of international law. This idea was expressed in his time by Prof. M.I. Lazarev, who noted that in the absence of special legal

[100] Monopolist in the field of artificial intelligence may become the ruler of the world [Electronic resource] // TASS.RU: TASS News Agency. 2019. 30 May. URL: https://tass.ru/ekonomika/6489864 (date of access: 30.05.2023).

provisions, innovations related to technological progress are subject to the general principles of international law[101]. Moreover, according to M.I. Lazarev, general principles of international law can serve as a criterion for the legality of the use of scientific and technological achievements[102].

However, it should be borne in mind that not only does STP have an impact on international law, but international law also has an impact on it. According to L.N. Galenskaya, STP acts as one of the main factors that influence the state of modern international law along with globalization and ecology[103]. Moreover, M.I. Lazarev believes that the achievements of science and technology can lead to the expansion of the scope of application of international legal principles and international law itself by including in the subject of regulation new social relations, the emergence of which is mediated solely by technological development (for example, cooperation in the field of creation and exchange of databases, as will be shown in § 4.2 of the dissertation)[104].

At the same time, the principles of international law, being too general in their content, often cannot be directly applied to specific issues arising in practice. At the same time, if we try to summarize the already existing international legal regulation of the use of the results of STP in health care, then already today we can deduce a number of general rules that define the basis for ensuring the safety of intrusion into the sphere of human health. From our point of view, summarizing the existing legal provisions, it is possible to derive a number of cardinal principles to which the use of scientific and technological achievements in healthcare should be subject[105]. Accordingly, these norms also apply to the use of artificial intelligence.

1. Responsibility of States for the health of their peoples (Preamble of the WHO Constitution, Art. V of the Declaration of Alma-Ata of 1978);

2. Respect for human rights, fundamental freedoms and dignity[106], including the right to the enjoyment of the highest attainable standard of health (Preamble of the WHO Constitution, Art. 12(1) of the International Covenant on Economic, Social and Cultural Rights of 1966, Universal Declaration on the Human Genome and Human Rights of 1997);

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[101] Lazarev M.I. Technical progress and modern international law : a monograph / M.I. Lazarev. Moscow: Gosurizdat, 1963. P. 17.

[102] Lazarev, M.I. International law and scientific and technological revolution / M.I. Lazarev // Soviet Yearbook of International Law, 1978. Moscow: Nauka, 1980. P. 44, 47, 48; Ioyrysh A.I. Op. cit. P. 14-15.

[103] Galenskaya, L.N. Trends in the development of legal regulation of international relations in the XXI century / L.N. Galenskaya // International relations and law: a glance into the XXI century: materials of the conference in honor of the Honored Scientist of the Russian Federation, Doctor of Law, Professor of the Department of International Law of the Faculty of Law of St. Petersburg State University L.N. Galenskaya (St. Petersburg, January 01 – December 31, 2009) / ed. by S.V. Bakhin. St. Petersburg, 2009. P. 28-42.

[104] Lazarev M.I. Op. cit. P. 44.

[105] Nikitenko S.V. International legal regulation of the use of artificial intelligence in the field of medicine. P. 219.

[106] Bakhin S.V. Scientific and technological progress in the field of medicine and international legal protection of human rights: autoref. diss. ... cand. juris. sciences: 12.00.10 / Bakhin Sergey Vladimirovich. St. Petersburg, 1990. P. 2.

3. Transition to universal health coverage (para. 2(d) of Art. 12 of the International Covenant on Economic, Social and Cultural Rights of 1966, Art. II of the Alma-Ata Declaration of 1978, WHO Resolution WHA67.23 of 24.05.2014[107]);

4. Ensuring the security of human health (Art. 3, 5 and 25 of the 1948 Universal Declaration of Human Rights, Art. 2, 7 and 12 of the 1966 International Covenant on Economic, Social and Cultural Rights, Preamble, Art. 1, 55 and 56 of the UN Charter and Preamble to the WHO Constitution)[108];

5. Cooperation among States, promotion of the free exchange of scientific knowledge and information in the fields of biology, genetics and medicine (Preamble of the WHO Constitution, Art. 19 of the Universal Declaration on the Human Genome and Human Rights of 1997, Art. 18 of the International Declaration on Human Genetic Data of 2003, par. 7 p. 1 of WHO Resolution WHA62.12 of 22.05.2009[109], par. 1 of WHO Resolution WHA60.29 of 23.05.2007)[110].

All the above principles can be regarded as emerging and even formed norms of international law. We say this with caution because some of them are enshrined in documents that are not of a legal nature. At the same time, they correlate with already existing norms of international law – either derived from or conjugated with them. At the very least, they should be included, in one form or another, in a future comprehensive international health treaty.

At the same time, a number of international legal instruments, both legally binding and of a recommendatory nature, postulate provisions that to date can only be regarded as declarative. For example, it is proposed to consider the so-called principle of solidarity as one of the principles of the activities of States in the field of health care[111]. According to this principle, states should ensure equitable distribution of costs and burdens in health care: those who suffer or are in the least favorable situation deserve assistance from those who can afford more expensive medical manipulations (Art. 17 of the Universal Declaration on the Human Genome and Human Rights of 1997, par. 6 of Article I of the UN Millennium Declaration of 2000[112], preamble of WHO Resolution WHA60.29 of 05.05.2007). In our view, this remains a stated goal for a number of countries, but is far from being realized in practice. Ensuring a fair distribution of the burden of health care costs is complicated by the costly nature of high-tech medical

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[107] Evaluation of health interventions and technologies to support universal health coverage: WHO resolution of 24.05.2014 № WHA67.23 [Electronic resource] // WHO: [website]. URL: https://apps.who.int/iris/rest/bitstreams/720885/retrieve (date of access: 30.05.2023).

[108] Bakhin S.V. Scientific and technological progress in the field of medicine and international legal protection of human rights: diss. ... cand. jurid. sciences. P. 137-140.

[109] Primary health care, including health systems strengthening: WHO resolution of 22.05.2009 № WHA62.12 [Electronic resource] // WHO: [website]. URL: https://apps.who.int/iris/bitstream/handle/10665/4381/A62_R12-ru.pdf?sequence=1&isAllowed=y (date of access: 30.05.2023).

[110] Bartenev D.G. Op. cit. P. 30-49.

[111] Ibid.

[112] UN Millennium Declaration of 08.09.2000 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/declarations/summitdecl.shtml (date of access: 30.05.2023).

care. It is quite evident that many medical manipulations using AI will require significant financial resources.

It is no accident that the 1966 International Covenant on Economic, Social and Cultural Rights (which enshrines, among other things, the right to health) provides that: « Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, particularly economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including in particular the adoption of legislative measures» (Art. 2, para. 1). The phrases «to the maximum extent of available resources» and «progressively» show that States were aware at the time of the adoption of the Covenant that guaranteeing social and economic rights by the State required financial investment, which could vary considerably from State to State. Therefore, it is premature to speak today about some common standards in the field of health care. The establishment of such standards will be complicated by the fact that they will be different for nationals and non-nationals of the host country[113].

However, some of the provisions proposed to be enshrined as fundamental principles in the field of health care can hardly be recognized as such. For example, a number of international documents enshrine the principle of prioritizing the interests and well-being of the individual over the rights and interests of society and scientific research (Art. 2 of the 1997 Oviedo Convention, WHO Resolution WHA69.24 of 28.05.2016[114], the preamble of the 2003 International Declaration on Human Genetic Data[115]). If the primacy of the interests and welfare of the individual over the interests of scientific research is hardly questionable, the primacy of the interests of the individual over the interests of society, at least in health care, is highly questionable. Of course, this is a subject for an independent in-depth study, but the attempt to put personal interests above public interests is not supported by all states. It is no coincidence that at the convention level this principle was enshrined only in the Oviedo Convention of 1997, developed within the framework of the Council of Europe, which is clearly dominated by individualistic tendencies.

Meanwhile, the whole practice of state cooperation in the field of public health, and especially the experience of the recent COVID-2019 pandemic, shows that in a number of cases, when it threatens public safety, it is it that will be the priority, rather than the rights of the individual. We find confirmation of this thesis in the norms of current international law. A number of articles of the 1966 International Covenant on Economic, Social and Cultural Rights (Art. 4 and 10) and the 1966 International Covenant

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[113] Bogdanova D.I. Cooperation of States to ensure the human right to receive medical care while outside their own state: autoref. diss. ... cand. jurid. sciences: 12.00.10 / Bogdanova Diana Igorevna. St. Petersburg, 2013. P. 1-28.

[114] Strengthening the mechanism of integrated people-centered health care: WHO resolution of 28.05.2016 № WHA69.24 [Electronic resource] // WHO: [website]. URL: https://apps.who.int/iris/bitstream/handle/10665/253412/A69_R24-ru.pdf?sequence=1&isAllowed=y (date of access: 30.05.2023).

[115] International Declaration on Human Genetic Data of 16.10.2003 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/declarations/genome_dec.shtml (date of access: 30.05.2023).

on Civil and Political Rights (Art. 12, 18, 19, 21 and 22) provide that the human rights enshrined therein may be restricted in the interests of public safety and public health. Therefore, in this part, the provisions of Art. 2 of the 1997 Oviedo Convention directly contradict the norms of fundamental universal human rights agreements. This issue is beyond the scope of the subject of this dissertation research. However, it is quite obvious that in the sphere of legal regulation of AI use sooner or later we will also have to face the competition of personal and public interests. In our opinion, the interests of public safety will also prevail here.

We do not claim that the above list of legal principles of utilization of STP achievements in healthcare is complete. In all likelihood, in the future use of both artificial intelligence and other technical innovations, it will have to be supplemented or clarified. However, it is clear that the future development of international medical law will require the establishment of two types of provisions. Firstly, general provisions concerning biomedical effects on human beings (Group 1), and secondly, safeguards to ensure safety in the performance of certain medical procedures (Group 2). In this respect, such guarantees are likely to be different for organ and tissue transplantation, human experimentation, reproductive manipulation and human genome editing, use of new diagnostic, prophylactic and treatment technologies. Artificial intelligence, as well as other scientific and technological innovations, can be used in any of the above spheres. Therefore, the regulation of its use can be repeated twice – in the 1st and 2nd groups.

The principles we have formulated above should, of course, be fixed precisely as legal principles. There are the following grounds for this assertion: they (1) are closely interrelated with the basic principles of international law, (2) are enshrined in the existing sources of international law, (3) allow to establish legal certainty, and (4) reflect objective regularities of the regulated relations[116].

[116] Yavich L.S. Law of developed socialist society : Essence and principles / L.S. Yavich. Moscow: Yurid. lit., 1978. P. 11.

§ 1.2. Patterns of international legal regulation of intelligent medical technologies

Many views AI as a «technological panacea» but as the authors of the WMA's 2019 Statement on Augmented Intelligence in Medical Care rightly point out, realizing the full benefits of intelligent medical systems may be hampered by increased oversight and demands for the safety and clinical efficacy of algorithms, lack of universally accepted standards, unresolved liability issues, lack of clear regulation of the use of personal data, and lack of unified. In this regard, the use of intellectual technologies in medicine, biology and pharmaceuticals requires special international legal regulation, taking into account the peculiarities of digital transformation of relations in the field of health protection, increased risk of discrimination and violation of human rights and freedoms, which is also emphasized in the Additional Protocol to the Oviedo Convention of 1997 of 27.11.2008 (CETS № 203).

Regulation of the use of AI in medicine can be carried out at both national and international levels, but priority should be given to the creation of unified international legal regulators. As Prof. S.V. Bakhin noted, the creation of the legal regime of technologies should begin with the formation of public-law principles (ensuring cooperation and security), without which the systematization of legal institutions (legal regime of the results of AI activities, tort liability, etc.) is not possible[117]. The legal regime of AI in healthcare should ensure, first of all, the safety of their use, as well as protect the rights and legitimate interests of the patient, which follows from Art. 2 of the 1997 Oviedo Convention and WHO Resolution WHA69.24 of 28.05.2016.

The subject of regulation of the use of AI includes relations related to the development, production, introduction into civil circulation, transportation, storage, sale, operation, maintenance and decommissioning of AI systems; relations of transboundary exchange of intellectual technologies and data; relations to ensure the safety of the use of AI in the provision of medical care and data processing[118]. However, it is impossible to unambiguously define the range of issues to be regulated due to the constant development of smart technologies. At the same time, as WHO pointed out as early as 2005 in its Resolution WHA58.28 on E-Health[119], the complication of these relations through the introduction of AI technologies makes it necessary to adapt existing international legal regulation to the conditions of digitalization of health care. Chapter 3 of the dissertation will be devoted to this issue.

Of fundamental importance are the issues of ensuring the interfacing of technical parameters, unification of requirements for AI safety, as well as free cross-border exchange of medical technologies and the results of their implementation in medicine, biology, and pharmacology. This position is

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[117] Bakhin S.V. Influence of New Technologies on Modern Private International Law. P. 106-138.

[118] Nikitenko S.V. International legal regulation of the use of artificial intelligence in the field of medicine. P. 221.

[119] E-health: WHO resolution of 25.05.2005 № WHA58.28 [Electronic resource] // WHO: [website]. URL: https://apps.who.int/iris/bitstream/handle/10665/20601/WHA58_28-ru.pdf (date of access: 30.05.2023).

confirmed in the WHO Resolution WHA71.7 of 05.05.2018 on «Digital Health»[120], which stresses the need for technical cooperation among States in standardization, interoperability of digital technologies, in particular through the development of affordable, efficient and adaptable technological solutions, as well as the establishment of bilateral, regional, interregional and global networks, digital platforms and information centers. Only broad international cooperation in the technical and standard-setting fields of subjects of international law can ensure effective and safe digitalization of national health systems[121]. In this regard, international cooperation plays a crucial role in regulating the use of AI technologies in the field of medicine and ensures that the risk of misuse is minimized.

In the context of regulation of any achievements of STP (including AI), we can note the subordinate position of law, the effective development of which is impossible without theoretical developments in related areas of knowledge[122]. According to the justified remark of A.V. Zazhigalkin, STP «influences not only the content, but also the form of law, its functions, the limits of legal regulation and the spatial scope of action», as well as the process of creation and implementation of legal norms[123]. International legal regulation of the use of AI should be based on objective regularities of (1) social relations in the sphere of utilization of STP results and health protection (were considered earlier), (2) provision of medical care (will be considered in Chapter 3 of the dissertation), (3) functioning of law as a regulator of social relations, (4) functioning of AI systems. Otherwise, as V.A. Dozortsev rightly noted, the violation of such regularities «sooner or later cruelly avenges itself»[124].

In the context of the rules that determine the structure, content and dynamics of law, the objective limits of legal regulation, which can be conditionally divided into two groups (according to the classification of N.A. Dmytryk)[125]:

1. External limits that arise as a result of the interaction between law and society. First of all, law operates on a certain territory and extends to a specific circle of persons, international law is no

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[120] Digital health: WHO resolution of 26.05.2018 № WHA71.7 [Electronic resource] // WHO: [website]. URL: https://apps.who.int/iris/bitstream/handle/10665/279508/A71_R7-ru.pdf?sequence=1&isAllowed=y (date of access: 30.05.2023).

[121] Please note that at present, given the geopolitical situation existing at the time of writing, it is expedient and effective for the Russian Federation to cooperate primarily with bona fide subjects of international law, which in the sense of Russian legislation are states that do not fall into the List of foreign states and territories committing hostile acts against the Russian Federation, Russian legal entities and individuals, approved by the Government Order This clarification should be taken into account in any reference to international cooperation within the framework of this dissertation research (for example, on pages 7, 14, 112, 113, 115, 134, etc.). See: p. 27-28 of the dissertation research.

[122] Nikitenko S.V. International Legal Regulation of Artificial Intelligence: Analysis of the Current State and Prospects of Development. P. 154.

[123] Zazhigalkin A.V. Scientific and technological progress and some problems of international law / A.V. Zazhigalkin // Scientific Notes of the St. Petersburg named after V.B. Bobkov branch of the Russian Customs Academy. V.B. Bobkov Branch of the Russian Customs Academy. 2003. № 1 (20). P. 286.

[124] Dozortsev V.A. Principle features of the right of ownership in the Civil Code / V.A. Dozortsev // The Civil Code of Russia. Problems. Theory. Practice: Collection in memory of S.A. Khokhlov / ed. by A.L. Makovsky. Moscow: Rhodes, 1998. P. 228.

[125] Dmitrik N.A. Limits of digital regulation in the digital era / N.A. Dmitrik // Information Society and Law. 2018. № 3. P. 50-57.

exception, since international obligations extend only to the subjects who have accepted such an obligation. As S.V. Chernichenko noted: «Interstate relations determine the objective boundaries of international law»[126]. In addition, not all aspects of private life can be the object of legal regulation, which is due to the objective impossibility or economic inexpediency of state intervention;

2. Internal limits associated with the intrinsic properties of law. In particular, the law, as a regulator of social relations, is designed for repeated application, which causes ignoring by the norms of law of some individual peculiarities. This problem cannot be solved by legal means, for example, by introducing abstract (rubber) norms or expanding the content of a legal norm, as this will only lead to destabilization of legal certainty and unknowability of the content of law. It is the cognizability of legal norms that is the second internal limit, since law is primarily information that must be perceived in order to have a regulatory effect.

To expand the internal limits (their non-exhaustion), the researchers propose to create a mechanism of «feedback» in the development of normative initiatives, which will allow to develop balanced and understandable legal norms[127]. The need for close interaction between the public and private sectors (government, business, science and consumers) is emphasized in the UNESCO Recommendation on the Ethical Aspects of AI of 2021 (par. 69). Establishing such mechanisms will also help to keep the law up-to-date, as participants in regulated relations are able to identify regulatory gaps in a timely manner and determine the need for changes[128].

In the field of AI regulation there is a problem of implementation of legal norms into the program code of the algorithm. Difficulties in this case arise both in the substantive, hermeneutical aspect (defining a set of specific, machine-executable rules that implement the content of a legal norm) and in the purely technical aspect in terms of translating legal prescriptions into binary code and ensuring their regulatory impact on the functionality of the program[129]. This field has a direct intersection with the field of mathematics and programming, which necessitates special interdisciplinary research in this area. Research of this kind is necessary because ensuring interoperability at syntactic and semantic levels with international norms and standards is one of the most important areas of effective and safe implementation of digital technologies (para. 28 of the WHO Draft Global Strategy for Digital Health 2020-2025[130]).

Cognizability as an internal limit of legal regulation is transformed into «programmability» of legal norms, under which we understand the possibility of practical embodiment of the relevant

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[126] Chernichenko S.V. Op. cit. P. 24, 29.

[127] Dmitrik N.A. Limits of digital regulation in the digital era / N.A. Dmitrik // Information Society and Law. 2018. № 3. P. 52.

[128] Willems A. Op. cit. P. 234.

[129] Sharkey N.E. The evitability of autonomous robot warfare / N.E. Sharkey // International Review of the Red Cross. 2012. Vol. 94. № 886. P. 789.

[130] Draft WHO global strategy for digital health for 2020-2025. [Electronic resource] // WHO: [website]. URL: https://www.who.int/docs/default-source/documents/200067-draft-global-strategy-on-digital-health-2020-2024-ru.pdf?sfvrsn=e9d760b3_2 (date of access: 30.05.2023).

prescriptions in the source code of the intellectual program. The topic of the dissertation does not cover the study of the problem of transformation of legal norms into a binary code, however, the very limit that should be taken into account when developing a special legal regime of artificial intelligence is of great importance for us.

Finally, a special set of international legal norms should reflect the balance of interests of all participants in relations complicated by AI[131]. Unjustified prioritization of any one group or public interest (dialectic of liberalism and protectionism[132]) without a proper legal and ethical basis may lead to a slowdown in the development and spread of AI, or to technological stagnation altogether. It is noteworthy that differently directed, at first glance, interests of social groups (developers, sellers, users, etc.) intersect in one thing – providing formal certainty, creating a set of generally binding rules, as justifiably noted by V.V. Arkhipov[133]. At the same time, according to Prof. O.N. Tolochko, legal regulation should ensure the creation of an innovative environment, i.e. such a system of social relations, in which technological projects and developments will be encouraged[134].

Thus, international legal regulation of the use of artificial intelligence for medical purposes should take into account not only the principles and norms of international law on the regulation of the achievements of STP and health protection, but also the peculiarities of medical care, socio-economic consequences of digitalization, technical aspects of the operation of AI systems[135], the interests of participants in the health care system, as well as the objective regularities of the functioning of law itself as a regulator of social relations (its internal and external aspects).

Summarizing the present chapter of the dissertation, we note that the totality of international legal norms regulating the use of intellectual technologies in medicine is inter-sectoral, in this regard, it will inevitably go beyond the limits of international medical law, because, as it was shown above, the solution of many problems related to the use of AI has a cross-cutting significance for the entire international law. It is therefore legitimate to assume that certain fundamental legal determinations will be common both within existing international legal institutions and newly emerging ones.

Regulation of smart technologies requires the promotion of international and multisectoral (public, private and non-profit sectors) cooperation to improve the compatibility of administrative and technical solutions. Relevant issues are (1) creation of a system of national standards of medical technologies and their harmonization on the basis of guidelines, (2) ensuring accessibility of technological medical

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[131] Nikitenko S.V. International Legal Regulation of Artificial Intelligence: Analysis of the Current State and Prospects of Development. P. 155.

[132] Willems A. Op. cit. P. 226.

[133] Arkhipov V.V. The problem of qualification of personal data as intangible goods in the conditions of digital economy, or there is nothing more practical than a good theory / V.V. Arkhipov. Arkhipov // Zakon. 2018. № 2. P. 56.

[134] Tolochko O.N. Trends of legal regulation of objects and technologies related to artificial intelligence / O.N. Tolochko // Justice of Belarus. 2019. № 3. P. 35-39.

[135] Nikitenko S.V. The principle of transparency as an integral part of the legal regime of artificial intelligence / S.V. Nikitenko // Eurasian Law Journal. 2022. № 3 (166). P. 39.

care, (3) improving its quality and safety, (4) promoting the dissemination of technologies in developing countries, (5) interstate exchange of information and experience.

CHAPTER 2. LEGAL STATUS OF ARTIFICIAL INTELLIGENCE FOR MEDICAL PURPOSES

§ 2.1. Legal capacity of artificial intelligence for medical purposes

The legal personality of artificial intelligence is one of the most debatable problems in the field of legal regulation of intellectual technologies. Recognition of AI as a subject will entail a cardinal transformation of the whole society, in particular, it will raise the question of inalienable rights of intellectual systems themselves[136]: the right to non-disabling against one's will, the right to access and protect one's own digital code[137], the right to create one's own copy[138] and others. Some researchers, in this connection, express the opinion that it is necessary to distinguish a special category of «AI-relationships»[139].

Already, as experts point out, one of the most important problems in robotics is the legal treatment of robots as quasi-agents, as over time algorithms are being given more and more functions previously performed by humans[140]. The European Parliament Resolution of 16.02.2017 № 2015/2103(INL) «On civil law rules on robotics»[141] (hereinafter – EU Resolution № 2015/2103) states that robots are increasingly becoming like agents that can interact with the environment and make significant changes to it, thus going beyond the role of a tool (points «AB» and «Z»). Further development of AI will lead to transformation of the basis of legal regulation of civil turnover and introduction of a new subject of relations with its own rights, obligations and mechanism of responsibility for its actions[142].

First of all, let us define the terminology used in this paragraph. Legal personality in the general theory of law, as a rule, is understood as the ability to possess subjective rights and obligations (legal capacity), as well as the ability to independently exercise such rights and obligations (legal capacity)[143]. This understanding of legal personality is fully applicable, including in the field of international law[144].

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[136] Uzhov F.V. Artificial intelligence as a subject of law / F.V. Uzhov // Gaps in Russian legislation. 2017. № 3. P. 359.

[137] Yastrebov O.A. Legal personality of an electronic person: theoretical and methodological approaches. P. 45.

[138] Dvorsky G. When the Turing Test is not enough: Towards a functionalist determination of consciousness and the advent of an authentic machine ethics [Electronic resource] // SENTIENTDEVELOPMENTS.COM: a personal blog of George Dvorsky. 2012. 1 March. URL: http://www.sentientdevelopments.com/2012/03/when-turing-test-is-not-enough-towards.html (date of access: 30.05.2023).

[139] Laptev V.A. Op. cit. P. 94.

[140] Asaro P.M. Robots and Responsibility from a Legal Perspective [Electronic resource] / P.M. Asaro // PETERASARO.ORG: personal website of Prof. Peter Asaro. 2007. URL: https://peterasaro.org/writing/ASARO%20Legal%20Perspective.pdf (date of access: 30.05.2023).

[141] Resolution (EU) № 2015/2103(INL) of 16.02.2017 with recommendations to the Commission on Civil Law Rules on Robotics // Offic. J. of the Europ. Union. Ser. C. 2018. Vol. 61, C252. P. 239-257.

[142] Zueva A.I. Op. cit. P. 76.

[143] Alekseev S.S. State and Law : beginning course / S.S. Alekseev. 2nd edition, revision and additions. Moscow: Yurid. lit., 1994. P. 93-95.

[144] Veliaminov G.M. International legal personality / G.M. Veliaminov // Soviet Yearbook of International Law. 1986 / Soviet Association of International Law. Moscow: Nauka, 1987. P. 85.

Many legal scholars consider legal personality as a combination of objective and subjective components, which demonstrates the dialectical unity of law in general[145], namely: (1) the abstract ability of a person to have rights and obligations, to act as a party to legal relations and (2) the possession of specific subjective rights and legal obligations, as well as the possibility of their independent realization[146].

In the framework of this dissertation, we will consider the category of legal personality in its abstract manifestation, i.e. as an objective possibility of AI to act as a participant of legal relations. The question of specific subjective rights and obligations, which an algorithm should possess, is the subject of a separate study and depends entirely on the solution of the problem of abstract legal personality of intellectual technologies.

The answer to the question of AI's legal personality depends on many variables, chief among which is its degree of autonomy and level of development[147]. In general, the need to recognize AI as a legal personality at a certain stage is supported by many authors due to the continuity of scientific and technological progress[148]. At the same time, the solution of the issue of technology controllability by a human being, being fundamental within the framework of the considered problematics, may not depend on the technological level of algorithm execution. In this regard, we must distinguish the legal status of two types of autonomous systems: AI under human control and without such control. At the same time, the problem of legal personality arises only in the second case: exercising control over the functioning of the algorithm does not naturally lead to the emergence of any subjectivity in AI at all[149].

We will start our reasoning with the «general part» applicable equally to any AI systems regardless of their purpose: we will address the content, role and transformation of the category of the subject of law in the modern era, and highlight the properties that are key to answering the question of legal personality of AI that is not under human control.

Legal reality is inherently divided into objects (what the action is directed at) and subjects (who performs these actions)[150]. This division reflects an exclusive anthropocentrism: law is seen as an area of human culture, created by and for human beings[151], who are recognized as the only actors, «ends in

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[145] Yavich L.S. On the philosophy of law for the XXI century / L.S. Yavich // Pravovedenie. 2000. № 4. P. 5.

[146] Margiev V.I. The concept of international legal personality / V.I. Margiev // Bulletin of the Adygeya State University. 2005. № 4. P. 134-136.

[147] Ponkin I.V. Op. cit. P. 96.

[148] Eidenmueller H. Op. cit.; Aristov E.V. To the issue of formation and development of the robot law (legal regulation of robotics) / E.V. Aristov, O.A. Kuznetsova // Science and education: economy and economics; entrepreneurship; law and management. 2018. № 8 (99). P. 60-61; Wein L. The Responsibility of Intelligent Artifacts: Toward an Automation Jurisprudence / L. Wein // Harvard Journal of Law & Technology. 1992. Vol. 6. Fall Issue. P. 105–106.

[149] Bakhin S.V. On the question of legal personality of artificial intelligence / S.V. Bakhin // Civil law in the era of transformation of social relations: materials of the international scientific-practical conference (within the framework of the annual civilist readings), dedicated to the 80th anniversary of the birth of Academician of the National Academy of Sciences of Kazakhstan, Doctor of Law, Professor M.K. Suleimenov (Almaty, September 30 – October 1, 2021) / edited by M.K. Suleimenov. Almaty, 2022. P. 474.

[150] Gabov, A.V. Legal personality: a traditional category of law in the modern era / A.V. Gabov // Bulletin of the Saratov State Law Academy. 2018. № 2 (121). P. 107.

[151] Gabov A.V. Legal personality: traditional category of law in the modern era. P. 106.

themselves»[152], whose subjectivity is not questioned. It is the person who is recognized as the beginning of the legal system, which determines its objective limits and peculiarities. At the same time, it should be noted that in this case we are talking about a person in a broad sense – not only as a separate physical person, but in general about individuals, social groups and organizations, including legal entities, states and humanity as a whole.

As V. Depad noted: «Among the fundamental principles of our legal system there is one <...> that distinguishes persons from things. The category of things is defined according to the residual principle in the sense that everything that is not a person is a thing. In this context, robots are things, and it doesn't matter <...> that their ability to learn allows them to get out from under the power of humans»[153]. In this context, some authors in principle question the possibility of replacing humans with robots, no matter how «human» they may be[154].

Since law is an element of human culture, the status of a particular element of reality as an object or subject of law depends, first, on the characteristics of the individual, the social groups and organizations he or she creates, as well as the relations into which such actors enter. For example, in the field of international law, the emergence of legal personality depends on the existence of sovereignty in a politically organized society in a certain territory or on the recognition of other sovereign power actors[155]. Similarly, legal entities within the framework of private legal relations arise only if a number of objective conditions are met (availability of separate property not lower than the minimum established value, founding document, etc.). Otherwise, the respective person or organization simply cannot exist and perform its functions.

Secondly, the decision on the issue of legal personality is largely predetermined by the discretion of the individual himself (including social groups and organizations), which, however, is not unlimited due to the objective limits of the law (mentioned in § 1.2 of the dissertation). The motives for granting the status of a subject of law are diverse and depend on a variety of sociocultural factors[156] (e.g., humanistic considerations[157]), the level of development of society, and its needs in a historically specific period of time[158]. A clear evidence of selective «subjectivization» is the slave system, under which slaves, being human beings, were legally considered objects of law.

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[152] Gadzhiev G.A. Is a robot agent a person? (Search for legal forms to regulate the digital economy) / G.A. Gadzhiev // Journal of Russian Law. 2018. № 1 (253). P. 21.

[153] Depadt V. La responsabilité: le point de vue du juriste // Lex Robotica: Le droit à l'épreuve de la robotique / Sous la direction de Valérie Depadt et Didier Guével. Paris: Lextenso éditions, LGDJ, 2018. P. 117.

[154] Melnikov V.S. Predictive modeling of artificial intelligence ontologies as a basis for designing necessary reference changes in legislation / V.S. Melnikov // Law and State: Theory and Practice. 2018. № 8 (164). P. 94.

[155] Chernichenko S.V. Op. cit. P. 228, 315.

[156] Arkhipov V.V. On some issues of theoretical foundations of the development of legislation on robotics: aspects of will and legal personality / V.V. Arkhipov, V.B. Naumov // Zakon. 2017. № 5. P. 162.

[157] Gabov A.V. Robot evolution and the law of the XXI century / A.V. Gabov, I.A. Khavanova // Bulletin of Tomsk State University. 2018. № 435. P. 221.

[158] Gabov A.V. Legal personality: traditional category of law in the modern era. P. 108.

These considerations lead us to the understanding of law as a special social reality with its own structure and order of functioning. To recognize something as a subject of law, special legal properties are important, which may be unrelated to the properties of «real»[159]. M. Hildebrandt's remark that modern positive law is itself an artificial artifact, which in textual form embodies the human will to transform the[160]. It should be taken into account that the subject of law is an artificial construct created by «jurisprudence <...> to describe legally significant factual compositions» (G. Kelsen), for which reason it is inadmissible to identify a person and the subject of law[161]. As J. C. Gray pointed out: «In writings on law, as well as in other works and everyday speech, ″subject″ is often synonymous with person, but from the standpoint of legal theory ″subject″ is the bearer of legal rights and duties»[162].

The subjective aspect of the issue of legal personality means that there is no universal concept of the subject of law compatible with any legal order: practically every state defines subjects of law in its own way, although there is little difference[163]. The explanation for this position lies in the already identified role of the human being as the main and only active beginning of all law[164]. The existence of internal and external limits of law, as well as objective regularities of social relations is a prerequisite for the unification of the legal status of AI at the international level.

The consolidation of a single concept of legal personality of AI in the sources of international law will allow to bring to uniformity the civil turnover (first of all, cross-border trade), will determine the specificity of the mechanism of liability for damage caused by algorithms, and will also predetermine the solution of the issue of ownership of rights to the results of AI-systems activity. The existence of a pre-formulated order and consequences of granting AI the status of a subject will help to prevent possible risks of the emergence of uncontrollable algorithms and their uncontrolled development in the future.

Considering the subject of law as a category with an autonomous content, the construction of a legal person, which should be considered more broadly through the designation of any subject within the framework of private legal relations, which is not a person, is subject to new understanding. The presented understanding of a legal entity is shared by the legal scholars of the pre-revolutionary period.

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[159] Arkhipov, S.I. Subject of law : a theoretical study / S.I. Arkhipov. SPb.: Legal Center Press, 2004. P. 120; Arkan Y.L. The philosophy of fictionalism of Hans Feichinger: the experience of retrospection and evaluation / Y.L. Arkan, Y.A. Solonin // Reflections on philosophy at the crossroads of the second and third millennia. 2002. № 11. P. 30-31.

[160] Hildebrandt M. The Artificial Intelligence of European Union Law // German Law Journal. 2020. № 21. P. 77.

[161] Kelsen G. Pure doctrine of law [Text] : (2nd ed., 1960) / G. Kelsen ; translated from German M.V. Antonov, S.V. Lyozov. SPb.: Aleph-Press, 2015. P. 212-219.

[162] Solum L.B. Legal Personhood for Artificial Intelligences [Electronic resource] / L.B. Solum // North Carolina Law Review. 1992. Vol. 70. № 4. P. 1231-1287. URL: http://scholarship.law.unc.edu/cgi/viewcontent.cgi?article=3447&context=nclr (date of access: 30.05.2023).

[163] Gabov A.V. Legal personality: traditional category of law in the modern era. P. 109.

[164] Mitskevich A.V. Subjects of Soviet law / A.V. Mitskevich. M.: State Publishing House of Legal Literature, 1962. P. 5; Stuchka P.I. Course of Soviet civil law / P.I. Stuchka. 2nd ed. M.: State Socio-Economic Publishing House, 1931. Vol. 1: Introduction to the theory of civil law. P. 133; Alekseev S.S. General theory of law : textbook / S.S. Alekseev. 2nd ed., revision and supplement. M.: Prospect, 2008. P. 379; Cherdantsev A.F. Theory of state and law : textbook for universities / A.F. Cherdantsev. M.: Yurait, 1999. P. 292; Marchenko M.N. Theory of state and law : textbook / M.N. Marchenko. Moscow: Yurid. lit., 1996. P. 360; Lazarev V.V. Theory of state and law / V.V. Lazarev, S.V. Lipen. 5th edition, revised and supplemented. M.: Yurait, 2015. P. 341.

According to K.D. Kavelin, persons in the legal sense are «persons <...> who are not human beings»[165]; S.V. Pakhman noted that such a person is recognized as «any abstract concept to which rights and obligations are assigned»[166]; According to D.I. Azarevich, a legal person should be considered «everything that, without being a human being, is capable of being a legal subject»[167].

As noted by A.V. Gabov, this approach will allow to recognize as a subject of law «an infinite variety of phenomena of reality»[168]. We are inclined to agree with this point of view, noting at the same time that the mentioned «infinite set» has its own objective limits (we have outlined earlier), and the subjects of law themselves must meet certain criteria, which will be discussed further in the dissertation research.

To illustrate the autonomous content of the category of legal entity and the subject of law in general, let us give a few real-life examples:

— in Russian law, according to clause 3 of Art. 1175 of the Civil Code, inherited property prior to its acceptance may act as an independent defendant;

— the U.S. Court of Appeals for the Ninth Circuit, in its decision Naruto v. Slater of 2018[169] held that the monkey owned the copyright to the photo, which was taken with a camera snatched from the photographer's hands;

— in the Kingdom of Saudi Arabia, Sophia, a humanoid robot with AI elements, has been granted citizenship[170];

— in some cases, the subject of law may be recognized as mankind. For example, in Art. 136 of the 1982 UN Convention on the Law of the Sea[171] the seabed and ocean floor, its subsoil and resources beyond the national jurisdiction of any state are the common heritage of mankind.

We can note in general the existence of a multitude of subjects within specific legal relations, branches of law and legal systems. Thus, in international law, subjects are recognized not only states and international organizations, but also peoples struggling for independence, state-like entities, and

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[165] Kavelin K.D. Rights and duties on property and obligations in application to Russian legislation : Experience of systematic review / K.D. Kavelin. SPb.: printing house of M.M. Stasyulevich, 1879. P. 17.

[166] Pakhman S.V. On the tasks of the forthcoming reform of the joint-stock legislation : A speech written to be delivered at the solemn meeting of the Imperial Kharkov University 30.08.1861 / S.V. Pakhman. Kharkov: University Printing House, 1861. P. 50.

[167] Legal entities [Electronic source] / D.I. Azarevich // Vremenik of Demidov Law Lyceum. Book 28 / A.A. Isaev, I.T. Tarasov, N.D. Sergeevsky [and others]. Yaroslavl: in the printing houses of the Provincial Board, the Zemstvo Office and Mr. Falke in Yaroslavl, 1882. URL: https://www.prlib.ru/item/328746 (date of access: 30.05.2023).

[168] Gabov A.V. Rightsubjectivity: traditional category of law in the modern era. P. 111; Gabov A.V. Evolution of robots and the law of the XXI century. P. 223.

[169] Naruto v. Slater, № 16-15469 [Electronic resource]: Appeal from the United States Court of Appeals for the 9th Circuit, filed 23 April 2018 // United States Courts for the 9th Circuit: [website]. URL: https://law.justia.com/cases/federal/appellate-courts/ca9/16-15469/16-15469-2018-04-23.html (date of access: 30.05.2023).

[170] Saudi Arabia was the first in the world to grant citizenship to a robot [Electronic resource] // KOMMERSANT.RU: «Kommersant» electronic print edition. 2017. 26 October. URL: https://www.kommersant.ru/doc/3450054 (date of access: 30.05.2023).

[171] UN Convention on the Law of the Sea of 10.12.1982 // CL RF. 1997. № 48. Art. 5493.

within the framework of individual international relations – subjects of federation, economic or customs unions, etc.

Thus, to date, multisubjectivity is already embedded in legal consciousness, national legal orders and international regulation, which indicates the flexibility of the category of the subject of law. As some authors rightly point out, nowadays «few people are confused by a view of the world in which the human being is not the only subject»[172], and the very notion that only the human being can be a subject « is becoming erroneous as being linked to a narrow realist understanding of law»[173].

At the same time, it would be wrong to assert that legally significant features are completely unrelated to the properties of the real world. Rather, some of such properties are given a legal meaning, and in this process can be traced its own regularity. In this context, we once again return to the anthropocentrism of law: the origins of subjectivity should be sought in the nature of the individual, social groups and organizations. It follows that the characteristics of the subject of law should be identified from (1) the specifics of social relations in which the actor participates or will participate, and (2) the peculiarities of such an actor itself, as well as (3) the presence of public interest in giving a separate element of reality legal personality. Obviously, the problem of AI legal personality should be considered within the framework of domestic and cross-border private legal relations, as algorithms are not sovereign or power actors.

To distinguish the signs of legal personality of AI we should be guided by the peculiarities and properties, first of all, of the participants of civil turnover – individuals and legal entities (organizations). At the same time, we must not allow legal characteristics to be confused with human properties through the active use of anthropomorphic terms (guilt, feelings, etc.)[174]. We believe that the main criterion of legal personality of participants of private legal relations is the presence of legal will, which is supported by many legal scholars (in particular, S.S. Alexeev[175], A.A. Vasiliev and D. Shpoper[176], S.V. Bakhin[177]).

However, there is no unambiguous understanding of legal will in legal doctrine, although many authors provide their own definitions: for example, according to G. Kelsen, will is the ability to legal imputation[178]. Analysis of scientific literature shows that a legally significant characteristic of the will is freedom of choice, autonomy in decision-making[179]. As Prof. S.V. Bakhin points out: «Legal will is the ability of a person to understand the meaning of his actions, to lead them <...>. The will directs the

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[172] Pelipenko A.A. Historical stages and levels of subjectivity evolution / A.A. Pelipenko // Subject in the time of social being: historical fulfillment of the space-time continuum of social evolution / ed. by E.V. Saiko. M.: Nauka, 2006. P. 72.

[173] Gadzhiev G.A. Op. cit. P. 20.

[174] Sharkey N.E. Op. cit. P. 795-796.

[175] Alekseev S.S. General Theory of Law. P. 379.

[176] Vasiliev A.A. The term «artificial intelligence» in Russian law: doctrinal analysis. P. 39.

[177] Bakhin S.V. Artificial intelligence as a subject of law. P. 768-769.

[178] Kelsen G. Op. cit..

[179] Gabov A.V. Legal personality: traditional category of law in the modern era. P. 116.

actions of a person to achieve a certain goal»[180]. This approach is followed by the EU, noting in para. 59 of EU Resolution № 2015/2103 that the special status of electronic persons may be granted to the most advanced robots that are capable of autonomous decision-making and autonomous interaction with third parties.

It is important to note that in this case we should distinguish between will as a legal and psychological category. For example, G.M. Veliaminov denies the legal assessment of the will as the basis of legal personality, noting that the will (along with emotions) is nothing more than a psychophysical phenomenon[181]. At the same time, this understanding of will clearly leads us to one conclusion – under this approach the only subject of will remains a capable natural person, while the will of other participants is a fiction. Such a position can negatively affect the stability of civil turnover, in particular, the legal personality of legal entities may be questioned[182].

In turn, legal will as a key prerequisite of legal personality consists in the subject's ability to make independent decisions and understand their meaning based on the analysis of available data and free choice of action alternatives. The analysis of AI attributes (listed in Appendix C) shows that legal will is a natural consequence of the dissident thinking activity that constitutes the intellectual autonomy of the algorithm. In addition, the algorithm may include criteria for legal assessment of a certain option of actions and consequences of decisions taken[183]. Therefore, we can reasonably argue that the legal will can be incorporated into the AI[184].

Thus, there is a prerequisite for conceptually recognizing the legal personality of AI. However, it should be noted that this conclusion does not indicate that all currently existing algorithms are autonomous and subjective. This issue depends on the technical execution of each algorithm, as well as on the specificities of the legal system, socio-economic, cultural and political factors. In this context, we note that in the spring of 2018, more than 150 specialists and experts in robotics, IT industry, law and ethics published an open letter to the European Commission, in which they pointed out that giving robots legal personality at the moment is premature from both ethical and legal points of view, although such a possibility is not excluded in the future[185].

An additional feature of the subject of law, in our opinion, is isolation[186]. In this case, we propose to distinguish between organizational (unity and integrity of the actor, including its governing bodies)

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[180] Bakhin S.V. Artificial intelligence as a subject of law. P. 768-769.

[181] Veliaminov G.M. National and international law. / G.M. Veliaminov ; Russian Academy of Sciences, Institute of State and Law. Moscow: RG-Press, 2017. P. 14-15.

[182] Bakhin S.V. To the question of the legal personality of artificial intelligence. P. 475.

[183] Ibid. P. 474.

[184] Bakhin S.V. Artificial intelligence as a subject of law. P. 768-769; Arkhipov V.V. On Some Issues of Theoretical Foundations... P. 161.

[185] Open letter to the European commission artificial intelligence and robotics [Electronic resource] // Robotics Open Letter: [website]. 2018. URL: http://www.robotics-openletter.eu/ (date of access: 30.05.2023).

[186] Bakhin S.V. To the question of the legal personality of artificial intelligence. P. 476.

and volitional separateness, by which we mean actual independence in the actor's decision-making and implementation. This feature reflects the premise stated at the beginning of this paragraph: as we pointed out earlier, the question of legal personality of AI is relevant only when it functions beyond human control.

In the scientific literature we can see other criteria of AI subjectivity. For example, a common position is that the prerequisite for legal personality is the ability to think. According to some authors, AI in principle will not be able to think like a human being, so it will always be a thing[187]. A related opinion is that only the ability to learn and improve oneself serves as a basis for recognizing legal personality. There are also such criteria as the presence of consciousness [188] or reasonableness[189]; the ability to bear legal responsibility, awareness and realization of one's own rights, interests and duties, the possibility of individualization[190]; subjective attitude to the acts committed and their consequences, as well as the presence of a sense of guilt[191].

Disclosure of the essence of the phenomena under consideration will be beyond the scope of this legal study, in this regard, we will limit ourselves to noting that there is no uniform understanding of such categories as consciousness, self-consciousness, soul, conscience, etc.[192], in the doctrine and even more so in the sources of law. This makes their legal qualification difficult (if not impossible). The other part of the criteria is already covered by the types of thinking activities we have considered (listed in Appendix C), are derived from the legal will[193] or do not affect the actor's separateness, therefore, they are indirectly related to legal personality. In addition, we must take into account the objective limits of legal regulation: it is unlikely that the above categories can be regulated by the norms of law.

In turn, the existence of (1) legal will, which is expressed through the capacity for autonomous thought, including the ability to make unprogrammed decisions, and (2) algorithm compartmentalization through the system's independent final decision-making – are relatively specific and practically applicable criteria that are also fully consistent with the legal nature of AI.

Finally, the position whose proponents deny the legal personality of AI due to the fact that the algorithm does not realize the content of legal prescriptions deserves attention. As M. Hildebrandt points out, mere perception and reaction are not enough: it is necessary that the algorithm can reorganize itself

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[187] Solaiman S.M. Legal personality of robots, corporations, idols and chimpanzees: a quest for legitimacy / S.M. Solaiman // Artificial Intelligence and Law. 2017. Vol. 25. № 2. P. 155-179; Bryson J.J. Robots Should Be Slaves [Electronic resource] // BATH.AC.UK: official website of the University of Bath. 2009. 6 June. URL: http://www.cs.bath.ac.uk/~jjb/ftp/Bryson-Slaves-Book09.html (date of access: 30.05.2023).

[188] Deva S. Can Robots have Human Rights Obligations? A Futuristic Exploration / S. Deva // The Law of the future and the future of Law. 2012. Vol. 2. P. 187; Gadzhiev G.A. Op. cit. P. 24.

[189] Yastrebov O.A. Legal personality of an electronic person: theoretical and methodological approaches. P. 50.

[190] Chernykh E.E. Digital medicine: risks of legal implementation of innovations in the field of health care / E.E. Chernykh // Legal Science and Practice: Bulletin of the Nizhny Novgorod Academy of the Ministry of Internal Affairs of Russia. 2020. № 4 (52). P. 87.

[191] Ibid.

[192] Solum L.B. Op. cit.

[193] Bakhin S.V. Artificial intelligence as a subject of law. P. 768-769.

to achieve the set goal, giving account of its actions. However, AI is based on calculation, not understanding[194]. In our opinion, legal understanding is important to the extent that it contributes to law enforcement. This component certainly matters to the human subject, who has no other way to follow the normative provisions than realizing the. In its turn, an AI-system is able to follow the norms of law (at least, in terms of compliance with obligations) without awareness – the relevant prescriptions can (and should) be embedded in the algorithm at the code level. Having the ability to make changes to the program and respond to commands will ensure that the AI's behavior can be adapted to the dynamic legal reality. For this reason, in our opinion, the ability to comply with legal norms is enough to be a subject of law.

Having answered positively to the question of the possibility of recognizing AI as an abstract legal personality, we are faced with the problem of the legal status of AI at present and in the near future. Current sources of international and integration law do not contain any concept of legal personality of algorithms at all, limiting themselves to the reservation on the need to develop a legal regulation that takes into account the autonomy of AI carriers (see EU Resolution № 2015/2103). For this reason, we are forced to turn to doctrine. According to the most widespread and currently relevant position, AI is exclusively an object of law. This approach is based on arguments about the absence of the key features of the subject of law inherent in a human being (consciousness, feelings, conscience, etc.). Proponents of the above concept do not deny that AI carriers should be given the status of a thing of a special kind[195]. In this regard, a number of researchers propose to extend the legal regime of animals to intellectual systems[196].

The advantage of the proprietary status of AI is that all rights to the results of AI activity and the algorithm itself belong to the owner, who has full freedom in extracting benefits from their use, which is especially relevant against the background of the high level of expenses (financial, time, organizational) for the creation of intelligent systems. At the same time, the proponents of this approach ignore the existence of legal will in AI as a general prerequisite for legal personality[197]. In this regard, some researchers express the view that AI should be considered both as an object and a subject of law («movable property endowed with limited legal personality»[198]) depending on the legal relations within the framework of which the algorithm is used[199]. For example, an industrial AI robot can act, on the one hand, as a participant of industrial and economic relations, but on the other hand, as a property that has

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[194] Hildebrandt M. Op. cit. P. 76-77.

[195] Ivanov A.A. Do androids dream about electric sheep? [Electronic resource] // ZAKON.RU: legal portal. 2017. 15 February. URL: https://zakon.ru/blog/2017/02/15/mechtayut_li_androidy_ob_elektroovcah (date of access: 30.05.2023).

[196] Petrenko M.N. Artificial intelligence: on the problems of legal status / M.N. Petrenko // Alley of Science. 2018. № 1 (17). P. 491-494.

[197] Vasiliev A.A. The term «artificial intelligence» in Russian law: doctrinal analysis. P. 39.

[198] Tsukanova E.Y. Legal aspects of liability for causing harm by a robot with artificial intelligence / E.Y. Tsukanova, O.R. Skopenko // Issues of Russian and international law. 2018. Vol. 8. № 4A. P. 45.

[199] Radutniy O.E. Op. cit. P. 138; Gadzhiev G.A. Op. cit. P. 22.

its own value[200]. The advantage of the concept is its flexibility in solving the issue of legal personality, however, this duality can lead to new difficulties related to the delimitation of subject-object spheres of relations. It is not excluded the existence of legal relations in which the algorithm can simultaneously act as an object and a subject, which will significantly complicate the implementation of applicable legal institutions.

The autonomy of AI systems causes the existence of a position in the scientific literature on the complete identification of the status of AI and human beings[201]. We believe that the legal identification of humans and intelligent systems is incorrect: algorithms should not in principle be analogous to humans. By adopting this approach, we are not talking about primary and secondary (as proposed by M. Benasayag[202]), but about equivalent subjects of law. For this reason, the scientific literature often contains proposals to develop a set of rights and obligations of the AI itself. At the same time, in this part we agree with I.N. Mosechkin, who noted that the above questions will be relevant from the moment of AI self-consciousness manifestation[203].

Finally, many researchers propose to give AI the status of a legal entity. We can conditionally divide the relevant concepts into two groups: (1) concepts of a legal entity in the broad sense as a construct different from a person; (2) concepts of a legal entity in the narrow sense as an organization in the sense of civil legislation.

To begin with, let us turn to «organizational» concepts. According to L. Solum, legal personality in this case is reduced to the possibility of intellectual systems to possess property rights, to bear responsibility independently, as well as to act as plaintiff and defendant in court on their own behalf[204]. As G.A. Gadzhiev points out, a developed AI can be recognized as a type of legal entity as a result of application of the technique of analogy as in the case of public-law entities[205]. A number of researchers point out that it is possible to recognize AI as a legal entity within the framework of already existing legislation without any amendments. For example, Sh. Bayern noted that U.S. corporate law allows for the creation of a corporation controlled by AI, making the algorithm a legal entity[206]. The case of «Tang

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[200] Laptev V.A. Op. cit. P. 88.

[201] Zimmerman E. Machine Minds: Frontiers in Legal Personhood [Electronic resource] / E. Zimmerman // SSRN Electronic Journal. 2015. 43 p. doi: 10.2139/ssrn.2563965.

[202] Benasayag M. Thinking beyond the brain [Electronic resource] / M. Benasayag // Courier UNESCO. 2018. № 3. P. 15-16. URL: http://unesdoc.unesco.org/images/0026/002652/265211r.pdf (date of access: 30.05.2023).

[203] Mosechkin I.N. Artificial intelligence and criminal responsibility: problems of formation of a new type of subject of crime / I.N. Mosechkin // Vestnik SPbU. Law. 2019. Vol. 10. № 3. P. 472.

[204] Solum L.B. Op. cit. P. 1231.

[205] Gadzhiev G.A. Op. cit. P. 24.

[206] Bayern Sh. The Implications of Modern Business-Entity Law for the Regulation of Autonomous Systems / Sh. Bayern // Stanford Technology Law Review. Vol. 19. № 93. P. 93-112.

Yu» Algorithm's appointment as CEO of NetDragon Websoft, a Chinese company, in August 2022 is also a good example of the implementation of this approach[207].

Extending the construction of a legal entity to algorithms naturally entails the need to apply by analogy the procedure of establishment and liquidation of an organization, as well as the attributes of a legal entity. For this reason, it is proposed to vest AI with rights and obligations from the moment of registration in a special register (e.g., the Unified State Register of Robots[208]) with the assignment of unique identifiers and simultaneous fixation in the register of information about the producers, owners and users of the algorithm[209]. Accordingly, likening AI to an organization will make it possible to keep records of operating systems, establish conditions for legitimizing their participation in civil turnover and cross-border trade, and formalize the moment when legal personality arises.

The analogy between legal entities and algorithms is most thoroughly reflected in the works of V.V. Arkhipov and V.B. Naumov, who note that there are no difficulties in extending the characteristics of a legal entity to AI: «Since this is a fiction, the problem of objective legal personality of robots does not arise in principle (no one says that legal persons are alive»[210]. In our opinion, this approach rather demonstrates a broad understanding of the legal person, which only deepens the meaning of the above quote.

This concept, however, has significant drawbacks. Thus, an unregistered algorithm does not lose its intellectual autonomy, which contradicts the key position on the relationship between will and legal personality. In addition, the presented approach is limited to the sphere of civil law, and is not applicable to legal relations in other areas. Associations of people in the form of various kinds of organizations and AI systems have different legal nature: the will of a legal entity is expressed through the decisions of its governing bodies, the existence of which is an indispensable condition for its legal personality[211]. In turn, the «substrate» of AI is not humans, but its own computational processes. As M. Benasayag points out: «Artificial intelligence by its very nature is not a human being or a fiction with a human behind it»[212].

The design of a legal entity-organization is intended to solve its own range of tasks: providing management, distribution of profits and responsibility. At the same time, the actual absence of separate management bodies and, as a consequence, the parties to corporate legal relations, causes the inapplicability of the full analogy of the signs of a legal entity to the AI. As A.V. Gabov and I.A. Khavanova

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[207] Sheremetev A. Chinese company has appointed artificial intelligence as a general director [Electronic resource] // HIGHTECH.FM: media portal about technologies «Hitech». 2022. 1 September. URL: https://hightech.fm/2022/09/01/robot-ceo-shina (date of access: 30.05.2023).

[208] Arkhipov V.V. On Some Issues of Theoretical Foundations... P. 166.

[209] Hallevy G. The Criminal Liability of Artificial Intelligence Entities – from Science Fiction to Legal Social Control / G. Hallevy // Akron Intellectual Property Journal. 2010. Vol. 4. № 2. P. 171-201.

[210] Arkhipov V.V. On Some Issues of Theoretical Foundations... P. 166-167.

[211] Tolochko O.N. Op. cit. P. 35-39.

[212] Benasayag M. Op. cit. P. 15-16.

rightly note: «an intelligent robot <...> is a new participant of social life <...>. And despite the standard approach to the creation of a new subject, its realization is impossible without the formation of new institutions»[213].

Attempts to formulate such new institutions are not isolated. Often, the researchers' proposals are limited to the statement of a new term without filling the proposed legal status of AI with a special content[214]. Among such positions, the theory of «incomplete legal entity» deserves attention[215], According to this theory, an AI system is endowed with a «truncated» legal personality[216] to the extent that depends on its technological peculiarities and functional purpose. There are a variety of variants of the designations of these persons: «robot»[217], «electronic person»[218], «electronic personality»[219], «artificial person»[220], «non-biological autonomous agent»[221] etc., which is of no essential importance[222]. The main discussion within the framework of this concept is focused on the criteria for determining the scope of rights and obligations with which the system should be endowed, as well as outlining the mechanism for changing the scope of legal personality depending on the dynamics of the development of AI.

A good example of such a concept is the initiative of D. Grishin, which is a special model for regulating relations in the field of robotics. In December 2016, a draft law «On Robotics» was presented by V.V. Arkhipov and V.B. Naumov[223]. The draft proposes to distinguish two independent categories: «robot» as a device capable of acting independently on the basis of incoming information, and «robot-agent» with special legal personality, which by decision of the owner and by virtue of design features is intended to participate in civil turnover[224]. A robot is recognized as an agent only if it is registered in a special registry and the owner makes a public statement about the start of the robot's operation in such status[225].

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[213] Gabov A.V. Evolution of robots and the law of the XXI century. P. 223.

[214] Baranov P.P. Op. cit. P. 42.

[215] Wein L. Op. cit. P. 107.

[216] Asaro P.M. Op. cit.

[217] Yurenko N.I. Robots – potential subjects of law: myth or reality / N.I. Yurenko // Innovations in science and practice: a collection of articles on the materials of the IV International Scientific and Practical Conference (Barnaul, December 19, 2017). Ufa, 2017. P. 45-47.

[218] Yastrebov O.A. Artificial intelligence in the legal space: conceptual and theoretical approaches. Yastrebov // Legal personality: general theoretical, sectoral and international legal analysis: a collection of materials for the XII Annual Scientific Readings in memory of Professor S.N. Bratusya / edited by V.F. Yakovlev, T.Y. Khabrieva, V.K. Andreev [and others]. M.: Institute of Legislation and Comparative Jurisprudence under the Government of the Russian Federation ; Statute, 2017. P. 271-283

[219] Beck S. Intelligent Agents and Criminal Law — Negligence, Diffusion of Liability and Electronic Personhood / S. Beck // Robotics and Autonomous Systems. 2016. Vol. 86. P. 140-141.

[220] Mossechkin I.N. Op. cit. P. 472.

[221] Richards N.M. How Should The Law Think About Robots? [Electronic resource] / N.M. Richards, W.D. Smart // SSRN Electronic Journal. 2013. P. 4. doi: 10.2139/ssrn.2263363.

[222] Gabov A.V. Evolution of robots and the law of the XXI century. P. 223.

[223] Robopravo [Electronic resource]: research center of regulatory problems of robotics and artificial intelligence / Neznamov A.V., Naumov V.B., Arkhipov V.V. [St. Petersburg], 2017-2020. URL: http://robopravo.ru/ (date of access: 30.05.2023).

[224] Arkhipov V.V. Artificial Intelligence and Autonomous Devices in the Context of Law. P. 50-51.

[225] Ibid. P. 52.

At the same time, the dual status of robots raises the question of the nature and scope of the robot-agent's property rights to the property transferred to it or acquired by it[226]. The proposed concept is generally considered by critics as dangerous for all participants of relations, except for manufacturers, and difficult to implement in practice[227]. While we do not share this opinion, we nevertheless agree with those researchers who note that the emergence of legal personality should not be made dependent on the realization of certain contractual constructions. From this point of view, it is more correct to divide algorithms into intellectual and non-intellectual, i.e. as acting under human control and outside of it[228].

The most appropriate concept, in our view, is to recognize AI as an entity of a special kind (sui generis) because algorithms (1) possess legal will and (2) can make final decisions without human intervention, i.e., can be autonomous. The granting of legal personality to AI should take into account the socio-economic, cultural and political factors of a particular national legal order. At the same time, the scope of such legal personality should be dynamic, i.e. it should depend on the field of application and the level of technological development of AI systems. In the field of medicine, the recognition of such a truncated legal personality of AI will make it possible to organize a fully autonomous process of medical care without human participation. However, given the current level of technological development, existing medical AI systems require increased human oversight.

The legal status of medical intelligent systems from the point of view of current regulation is a rather definite issue. The lack of legal personality of algorithms is not disputed, since currently clinical AI systems function exclusively under human control (as systems of so-called «augmented intelligence» according to the terminology of WMA specialists[229]). By their nature, intelligent systems are software with a number of special properties (see Appendix C for details). In this connection, the existing software and devices with AI elements are considered as (1) a result of intellectual activity (as a rule, a computer program) and (2) a medical product, which entails the extension of procedures for control over the circulation of medical devices to the relations associated with the development, introduction into civil circulation and further operation of such products.

At the same time, the qualification of the legal status of «non-subject» AI also gives rise to a number of difficulties. First of all, the question arises: intellectual developments are objects of copyright, patent protection or they should be considered unique results of intellectual activity that require special regulation at all? In this context, we are in solidarity with Prof. O.N. Tolochko, who argues that the

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[226] Ivanov A.A. Op. cit.

[227] Shukhov Lab hosted Tech Breakfast «Modern City, Artificial Intelligence and Robotics Legislation: What Should They Be?» [Electronic resource] // URBAN.HSE.RU: news section of the website of the A.A. Vysokovsky Higher School of Urban Studies. 2017. 10 February. URL: https://urban.hse.ru/news/206795842.html (date of access: 30.05.2023).

[228] Laptev V.A. Op. cit. P. 94.

[229] See: WMA Statement on augmented intelligence in medical care. URL: https://www.wma.net/policies-post/wma-statement-on-augmented-intelligence-in-medical-care/ (date of access: 30.05.2023).

emergence of AI cannot be considered as a revolution in the field of intellectual property[230], since algorithms are software expressed through machine-readable code (i.e. in an objective form). We do not deny that AI complicates a number of legal institutions and procedures related to the establishment of authorship and ownership of rights to the results of intellectual systems. Consideration of these problems is beyond the scope of this dissertation research, but it certainly requires a separate study.

Analysis of international legal acts and legal doctrine shows that the most common position is that intellectual systems are subject to protection as objects of copyright, namely computer programs («computer programs» in the terminology of Russian legislation), which in their status are equal to literary works. This concept is enshrined in the WIPO Copyright Treaty of 1996[231] (Art. 4) and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994 (Art. 10, para 1) (hereinafter referred to as the TRIPS Agreement of 1994). In turn, the legal regime of literary works was defined as early as in the Berne Convention for the Protection of Literary and Artistic Works of 1886[232].

The advantages of this approach are the absence of costs associated with the provision of copyright protection, which arises automatically from the moment of creation of the work. This regime provides the right holder with effective legal remedies against circumvention of technical means aimed at protecting the result of intellectual activity from illegal use (for example, cryptographic encryption methods). We find the relevant provisions in Article 11 of the 1996 WIPO Copyright Treaty, as well as in Article 6 of the EU Directive № 2001/29/EC of 22.05.2001 «On the harmonization of certain aspects of copyright and related rights in the information society»[233].

At the same time, copyright protection extends only to the source code and object code of an algorithm. The exclusive copyright prevents copying of such code or its revision, however, it does not protect the very method of its application, data processing methods or the hardware solution in which the corresponding software was embodied. In addition, copyright infringement of program code is rather difficult to detect, since access to the source code of the software underlying the competing development is usually closed.

Such a method of intellectual property protection as patenting an algorithm as an object of industrial property (invention or utility model), the international legal regime of which is established in the Paris Convention for the Protection of Industrial Property of 1883[234] and the TRIPS Agreement of

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[230] Tolochko O.N. Tendencies of legal regulation of objects and technologies related to artificial intelligence. P. 35-39.

[231] WIPO Copyright Treaty and Agreed Statements Concerning the WIPO Copyright Treaty: Adopted by the Diplomatic Conference on December 20, 1996, Geneva // International Treaty Bulletin. 2016. № 12. P. 4-11.

[232] Berne Convention for the Protection of Literary and Artistic Works of 09.09.1886, as amended on 28.09.1979 // Bulletin of International Treaties. 2003. № 9. P. 3-34.

[233] Directive (EU) № 2001/29/EC of 22.05.2001 on the harmonisation of certain aspects of copyright and related rights in the information society // Offic. J. of the Europ. Comm. Ser. L. 22.6.2001. L167. P. 10-19.

[234] Paris Convention for the Protection of Industrial Property of 20.03.1883, as amended on 02.10.1979 // Zakon. 1999. № 7.

1994, is devoid of these disadvantages. At the same time, patent protection of AI developments is associated with significant financial and time costs for preparing a patent application and going through all the required procedures. Moreover, due to the territorial principle of patent protection (Art. 4bis of the Paris Convention of 1883), patented subject matter is subject to protection only in the state where the patent was obtained, unlike copyright protection, which applies equally to all parties to relevant international agreements (as a rule, WIPO members).

In the world practice we can also find cases when innovative developments are protected as production secrets (know-how)[235], which are subject to the trade secret regime. This method of protection allows to avoid the costs associated with obtaining a patent, provides protection of the relevant result of activity from the moment of creation, and also allows to protect scientific and technological achievements in conditions of increased mobility of developers[236]. At the same time, the protection of the result of intellectual activity as a production secret is a rather «fragile» tool to protect the interests of right holders, since the protection is terminated from the moment when the confidentiality regime of the development has been violated. Therefore, algorithms whose right holders are confident in their sufficient complexity and immunity to engineering analysis by competitors are protected as trade secrets.

Historically, patent protection was the first method of intellectual property protection, as the first computing systems were inextricably linked to hardware, so that software and hardware were virtually inseparable. However, the further development of technology, especially the emergence of personal computers, led to the need to establish a special legal regime of computer programs, which became «independent» of a particular electronic computer and, thus, could be an independent object of civil turnover. It is noteworthy that WIPO in 1983 presented its own draft international treaty on software regulation, which combined elements of patent and copyright law. However, this project was not supported because by that time the problem of establishing the legal regime of programs had already been successfully solved by extending copyright protection to such results of intellectual activity[237].

The previously mentioned ambiguity of the status of medical AI technologies leads us to the question of cases where intelligent software is also a medical device. We will find the criteria for classifying software as a medical device in the Guidelines «Software as a Medical Device (SaMD): Key Definitions» of 2013[238], developed by IMDRF – an international non-governmental organization, which

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[235] Gorodov O.A. Patenting of inventions, utility models and industrial designs in foreign countries / O.A. Gorodov // Patents and licenses. Intellectual rights. 2016. № 6. P. 8-13.

[236] Kaisner E. Robotics: breakthrough technologies, innovations, intellectual property / E. Kaisner, D. Raffo, S. Wunsch-Vincent // Foresight. 2016. Vol. 10. № 2. P. 24.

[237] Shtolyakov V.I. Emergence of legal protection of computer programs and databases / V.I. Shtolyakov, M.V. Yaganova // Bulletin of Ivan Fedorov MSUE. 2015. № 1. P. 185.

[238] Software as a Medical Device (SaMD): Key Definitions [Electronic resource]: Final Document, WG/N10FINAL:2013 [Electronic resource] // IMDRF: [website] / IMDRF SaMD Working Group. 2013. URL: https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.docx (date of access: 30.05.2023).

unites representatives of government agencies and aims to harmonize the legal regime of medical devices (a representative from Russia has been participating in the Forum since 2013).

Thus, the Guidelines propose to distinguish between software as a part of a medical device (in which case the algorithm is not an independent product) and software as a separate medical device. The classification criterion is the functional purpose and ability of the software to fulfill its clinical tasks. Software is a medical device if it is both: (1) a computer program capable of operating without being tied to a specific hardware platform and software; (2) not an integral part of another medical device; and (3) intended by the manufacturer to provide medical care.

The above criteria were transferred to the Recommendation of the Board of the Eurasian Economic Commission № 25 of 12.11.2018 «On the criteria for classifying products as medical devices within the EAEU»[239] and supplemented with the following condition (clause 18): the result of the program should be the interpretation of data in automatic mode, including the use of AI-technologies, or according to the parameters set by the medical worker, influencing clinical decision-making. This condition allows computer programs designed to perform non-intellectual operations, for example, to convert measurement values, to be excluded from the medical devices circulation regime.

This list of conditions is verbatim transferred to the domestic level, as evidenced by paragraph 2.10 of the National Standard GOST R 59921.2-2021 «AI systems in clinical medicine. Part 2. Program and methodology of technical tests»[240]. As of August 2020. Software that is a medical device is included in the Nomenclature Classification of Medical Devices by Type[241]. Thus, singling out smart software as a stand-alone medical device is a widespread approach.

The qualification of clinical AI systems as medical devices naturally entails the extension to the relations related to the use of such systems of a special treatment of medical devices, within the framework of which special safety and quality requirements are imposed on the manufacturers and the algorithms themselves, which will be discussed in more detail in § 3.3 of the dissertation. For the time being, we note that recognizing AI as a medical device is reasonable and has the potential to positively impact the healthcare system through the establishment of an effective quality control mechanism. Ultimately,

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[239] On criteria for attributing products to medical devices within the EAEU: Recommendation of the Board of the Eurasian Economic Commission № 25 of 12.11.2018, as amended on 30.05.2023 [Electronic resource] // Reference legal system «ConsultantPlus». Access mode: http://www.consultant.ru/.

[240] GOST P 59921.2-2021. Artificial intelligence systems in clinical medicine. Part 2. Program and methodology of technical tests [Electronic resource] ; introduced 2022-03-01 // Federal Agency for technical regulation and metrology: [website]. Moscow, 2021. URL: https://protect.gost.ru/v.aspx?control=8&baseC=6&page=0&month=5&year=2022&search=59921.2–2021&RegNum=1&DocOnPageCount=15&id=232102 (date of access: 30.05.2023).

[241] On Approval of the Nomenclature Classification of Medical Devices (together with «Nomenclature Classification of Medical Devices by Type», «Nomenclature Classification of Medical Devices by Class depending on the Potential Risk of their Use») : Order of the Ministry of Health of Russia from 06.06.2012 № 4n, ed. from 07.07.2020 // Rossiyskaya Gazeta. 2012. № 245.

this will ensure the introduction of safe technologies into medical practice, which is the main objective of legal regulation in this area.

§ 2.2. Legal principles of artificial intelligence regulation

Artificial intelligence, being one of the most important technologies ensuring digitalization of the world economy in general and healthcare in particular, naturally requires the formation of its own international legal regulation, taking into account the specifics of the technology regardless of the sphere of application. In order to develop effective and consistent legal norms, fill gaps and resolve conflicts arising in various branches and institutions of international law in connection with the use of intellectual technologies, we must, first of all, form special legal principles to regulate the considered group of social relations[242].

Attempts to form principles of regulation of AI systems have already been made, both in international (UNESCO Recommendation on the Ethical Aspects of AI of 2021 and the Principles for the Ethical Use of AI in the UN System of 2022, developed on its basis by the UN System Chief Executives Board for Coordination[243]), integration (EU Regulation № 2015/2103, draft EU Regulation on Harmonized Rules on AI of 16.05.2023 or the so-called «AI Act»[244]), as well as domestic law (clause 19 of the National Strategy for the Development of AI until 2030[245] (Russian Federation); Blueprint for an AI Bill of Rights of 2022[246] and the National AI Initiative Act of 2020[247] (USA); AI Sector Deal of 2018[248] and National AI Strategy of 2021 г.[249] (UK); Next Generation AI Development Program of 2017[250], Position

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[242] Ponkin I.V. Op. cit. P. 93.

[243] Principles for the Ethical Use of Artificial Intelligence in the United Nations System: prepared by Inter-Agency Working Group on Artificial Intelligence 20.09.2022 [Electronic resource] // The UN System Chief Executives Board for Coordination: [website] / High-Level Committee on Programmes. URL: https://unsceb.org/sites/default/files/2022-09/Principles%20for%20the%20Ethical%20Use%20of%20AI%20in%20the%20UN%20System_1.pdf (date of access: 30.05.2023).

[244] Proposal for a Regulation (EU) on harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts: Draft Compromise Amendments on the Draft Report, Ver. 1.1 of 16.05.2023 [Electronic resource] // European Parliament: [website]. URL: https://www.europarl.europa.eu/resources/library/media/20230516RES90302/20230516RES90302.pdf (date of access: 30.05.2023).

[245] On the development of artificial intelligence in the Russian Federation (together with the «National Strategy for the Development of Artificial Intelligence for the period up to 2030») : Decree of the President of the Russian Federation of 10.10.2019 № 490 // CL RF. 2019. № 41. Art. 5700.

[246] Blueprint for an AI Bill of Rights [Electronic resource] // The White House, USA: [website] / Office of Science and Technology Policy. Washington, 2022. URL: https://www.whitehouse.gov/ostp/ai-bill-of-rights/ (date of access: 30.05.2023).

[247] The National AI Initiative Act of 2020 (Division E) // William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 : conference report / W.M. (Mac) Thornberry. Washington: U.S. Government publishing office, 2020. P. 1164-1188.

[248] AI Sector Deal: Policy paper [Electronic resource] // Government of the United Kingdom: [website] / Department for Business, Energy & Industrial Strategy ; Department for Digital, Culture, Media & Sport. London, 2018. 26 April. Last updated: 21.05.2019. URL: https://www.gov.uk/government/publications/artificial-intelligence-sector-deal/ai-sector-deal (date of access: 30.05.2023).

[249] National AI Strategy: Guidance [Electronic resource] // Government of the United Kingdom: [website] / Department for Business, Energy & Industrial Strategy ; Department for Digital, Culture, Media & Sport ; Office for Artificial Intelligence. London, 2021. 22 September. Last updated: 18.12.2022. URL: https://www.gov.uk/government/publications/national-ai-strategy/national-ai-strategy-html-version (date of access: 30.05.2023).

[250] New Generation Artificial Intelligence Development Program: approved by the State Council of the People's Republic of China on 08.07.2017, index 000014349/2017-00142 [Electronic resource] // State Council of the People's Republic of China: [website]. URL: https://www.gov.cn/zhengce/content/2017-07/20/content_5211996.htm (date of access: 30.05.2023).

Paper of the People's Republic of China on Strengthening Ethical Governance of AI of 2022[251] and the 14th Five-Year Plan[252] (China); Artificial Intelligence and Data Act of 2022[253] (Canada); Draft AI Regulatory and Ethics Policy of 2022[254] (Israel); AI Ethics Principles of 2022[255] (Kingdom of Saudi Arabia), etc.).

However, those normative provisions that we can find in existing international legal and domestic normative acts, as well as other official documents, do not form a coherent system: each subject of international law adopts its own list of norms of general order, the scope and content of which may vary significantly. At the same time, a number of normative provisions are systematically repeated, which indicates the formation of a uniform approach to the regulation of AI technologies in this part, and allows us to conclude that such norms are of fundamental importance.

The analysis of existing sources of international and integration law allows us to deduce the following fundamental normative provisions in the field of AI regulation:

— principle of informed consent;

— principle of safe use;

— risk management principle;

— transparency principle.

These principles, in our opinion, should be fixed precisely as international legal ones, since such principles are reflected in the majority of existing sources of international, integration and domestic law, as well as enshrine objective regularities of relations in the field of AI. The legal principles of AI regulation formulated by us are equivalent and should be considered as an integral part of the system of international law. Let us consider the content of each of these special legal principles in more detail.

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[251] Position Paper of the People's Republic of China on Strengthening Ethical Governance of Artificial Intelligence [Electronic resource] // Ministry of Foreign Affairs of The People's Republic of China: [website] / Ministry of Foreign Affairs of The People's Republic of China. Beijing, 2022. 17 November. URL: https://www.fmprc.gov.cn/mfa_eng/wjdt_665385/wjzcs/202211/t20221117_10976730.html (date of access: 30.05.2023).

[252] Plan focuses on digital economy development during 14th Five-Year Plan period [Electronic resource] // The State Council of The People's Republic of China: [website] / Xinhua. Beijing, 2022. 12 January. URL: https://english.www.gov.cn/policies/latestreleases/202201/12/content_WS61de9a35c6d09c94e48a385f.html (date of access: 30.05.2023).

[253] Artificial Intelligence and Data Act: Part 3 of Bill C-27, first reading in House of Commons of Canada 16.06.2022 [Electronic resource] // Parliament of Canada: [website]. Ottawa, 2022. URL: https://www.parl.ca/DocumentViewer/en/44-1/bill/C-27/first-reading (date of access: 30.05.2023).

[254] Draft AI Regulatory and Ethics Policy: published by the Israeli Ministry of Innovation, Science and Technology on 30.10.2022 [Electronic resource] // Government of Israel: [website]. URL: https://www.gov.il/he/departments/news/most-news20223110 (date of access: 30.05.2023).

[255] AI Ethics Principles: prepared by Saudi Data and Artificial Intelligence Agency in August 2022, ver. 1.0 [Electronic resource] // The Saudi National Competitiveness Center: [website]. URL: https://istitlaa.ncc.gov.sa/en/transportation/ndmo/aiethicsprinciples/Documents/AI%20Ethics%20Principles.pdf (date of access: 30.05.2023).

2.2.1. The principle of informed consent

In our opinion, within the framework of legal regulation of relations complicated by AI, the principle of interaction with intellectual technologies on the basis of informed consent should be separately emphasized. This principle expresses the autonomy of a person who, on the basis of information about the technology, guided by his interests and experience, makes his own decision regarding the possibility and method of interaction with intelligent algorithms, and is responsible for his life, health and well-being.

Any interaction with intelligent technologies should, as a general rule, be based on voluntary and informed consent, whereby the person concerned is provided with information about the functioning of the AI, including information about the decision-making logic and predictions for the development of the technology. Such consent should be complete and understandable, in this regard, the volume and composition of information should dynamically change depending on the qualification of the person concerned. The need to obtain consent is already stipulated as a condition for medical intervention and personal data processing, which allows us to judge the universality of this rule for the regulation of AI.

In the case of smart technologies, the principle of informed consent also implicitly assumes the existence of a non-automated alternative to the procedure, service or other good in question. In the field of medicine, the realization of the principle should imply giving the patient a choice of the mode of health care delivery: fully automated, non-automated, or mixed.

The principle of informed consent has its own limits. For example, a medical intervention may be carried out without the patient's consent in the case of a threat to the patient's life and health in an emergency situation (this issue is discussed in more detail in § 3.1 of the dissertation). The validity of the principle of informed consent in this case means that all exceptions and limitations to this principle must comply with the criteria of legality, necessity and proportionality of such interventions as set out in Art. 26 of the 1997 Oviedo Convention and Art. 29(2) of the 1948 Universal Declaration of Human Rights.

Some authors highlight the principle of «meaningful participation» in AI-relations, the essence of which consists in realizing the risks of violation of rights and legitimate interests, as well as causing harm as a result of the use of algorithms. Central to this principle is (1) the mechanism for providing information about the algorithm, (2) ensuring the interpretability of intelligent systems' decisions, (3) user compliance with instructions, AI guidelines, and reasonable behavior in emergency situations[256]. However, an analysis of the content of «meaningful participation» shows that this principle is practically fully covered by the principles we have already outlined. Once the overlapping areas are removed from

[256] Rassolov I.M. On the use of artificial intelligence in the legal protection of genetic information / I.M. Rassolov, S.G. Chubukova // Scientific Proceedings of the Russian Academy of Advocacy and Notaries. 2021. № 1 (60). P. 87.

the principle of «meaningful participation», we will be left with a general rule of good faith and reasonable behavior, which outside the private law sphere (where it is already covered by the corresponding principle of good faith) is no more than an ethical norm.

2.2.2. Principle of safe use

The issue of safety of AI use in medicine is of paramount importance, since life and health are among the main (if not the main) values of human society. We believe that the requirement to ensure the safety of algorithm use should extend to all areas of AI use, thus acquiring the significance of a universal legal principle. Otherwise, the lack of adequate mechanisms to ensure the development and admission into circulation of safe and human-controlled intelligent systems will create a real threat of irreparable harm to the environment and human society through unlimited impact on nature and resources, as well as the purposeful use of technological advances to harm protected human values, rights and legitimate interests. The risk of global negative consequences from uncontrolled development of technologies prompts many AI researchers and IT-industry figures to insist on the necessity of a temporary moratorium on the development of new «advanced» intelligent systems.

The realization of the principle of safe use is achieved through the adoption of special international, national and industry standards in the field of development, introduction into civil circulation and operation of intelligent systems, introduction of a system of public quality control of AI-developments (through mandatory registration or independent certification), ensuring information security (confidentiality of personal data), as well as a balanced and effective mechanism for the distribution of responsibility[257]. Each of these areas of safety assurance will be discussed separately in Chapter 3 of this dissertation. Ensuring the qualifications of operators of AI systems is of no small importance[258].

Analysis of the sources of international law shows that along with security aimed at eliminating or minimizing the risks of harm to protected values, rights and legitimate interests, there is also a requirement to ensure the security (or reliability) of AI systems, the essence of which is the security of the algorithms themselves (para. 27 of the 2021 UNESCO Recommendation on the Ethical Aspects of AI, para. 1.4 of the 2019 OECD Recommendation on AI). In our opinion, the security of algorithms is subject to legal regulation insofar as it may affect the safety of the use of AI. Therefore, these regulations can be incorporated into the principle of safety in the use of AI, which thus becomes the normative basis for the relevant requirements.

In order to ensure safety, researchers attach great importance to the ethical guidelines that are embedded in the code of an algorithm. The scientific literature offers many variants of moral frameworks

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[257] Kaisner E. Op. cit. P. 17.
[258] Bakhin S.V. Influence of new technologies on modern international private law. P. 106-138.

and rules that should be included in the algorithm for its safe operation. Despite the diversity of positions and the complexity of the issue at hand, we can identify a number of ethical rules that are most commonly found in sources of law and doctrine.

Thus, researchers propose to introduce a categorical imperative into AI[259]. However, in our opinion, it is unlikely that this rule can be translated into program code without losing its meaning: we will inevitably encounter formalization of the imperative in the form of enumerating specific prescriptions, criteria for determining ambiguous situations and choosing strategies of action. In addition, as experts note, the existing algorithms are only able to solve the problem of «simple» proportionality (ratio of quantitative values) and in general are unable to show empathy and functional morality based on understanding of the situation, but not automatic reaction to input signals[260].

Speaking of concrete and formally defined rules, we cannot but mention the «three laws of robotics», which were developed by A. Asimov[261], namely: (1) a robot cannot harm a human being or by its inaction allow a human being to be harmed; (2) a robot must obey all orders given by a human being, except when these orders contradict the first law; (3) a robot must take care of its own safety, if it does not contradict the first and second laws. These rules are sufficiently definite that they can be implemented in AI. The idea of making these rules legal is not new. Thus, the General Principles section of the Introduction to EU Resolution № 2015/2103 states that it is Asimov's laws of robotics that must be considered by designers, manufacturers and operators of robots, including autonomous and self-learning robots, if they cannot be converted into machine code.

In our opinion, only the first two laws can be relevant at present – due to the lack of universal functionality and independent goal-setting, it is rather premature to speak about the emergence of algorithms' «quasi»-right to self-preservation. At the same time, it is the first law (of not harming a person) that is primary. Some researchers have noted that these laws (or ethical heuristics[262]) can be formalized as legal prescriptions in a framework similar to privacy by design in the field of personal data[263]. As we will point out in § 3.3 of the dissertation, the principle of protection by design should be introduced for the legal regime of AI-technologies, the essence of which will consist in embedding in the algorithm of software measures aimed at preventing[264] and minimizing harm, including through the inclusion of these laws in the algorithm code.

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[259] Harris J. Reading The Minds of Those Who Never Lived. Enhanced Beings: The Social and Ethical Challenges Posed by Super Intelligent AI and Reasonably Intelligent Humans / J. Harris // Cambridge Quarterly of Healthcare Ethics. 2019. Vol. 28. № 4. P. 1-7.

[260] Sharkey N.E. Op. cit. P. 789, 794 ; Zueva A.I. Op. cit. P. 78.

[261] Asimov A. Robotaround. N.Y.: Basic Books, 1960. P. 129.

[262] Zhuravleva A.V. Ethical issues of artificial intelligence: a bridge between man and technology / A.V. Zhuravleva // Theory of Law and Intergovernmental Relations. 2021. Vol. 1. № 1 (13). P. 150.

[263] Arkhipov V.V. On some issues of theoretical bases for the development of legislation on robotics: aspects of will and legal personality / V.V. Arkhipov, V.B. Naumov // Zakon. 2017. № 5. P. 169.

[264] Mosechkin I.N. Artificial intelligence and criminal responsibility: problems of formation of a new type of subject of crime / I.N. Mosechkin // Vestnik SPbU. Law. 2019. Vol. 10. № 3. P. 467.

Due to the lack of a functioning system of international technical regulations and standards in the field of AI, the experience of specialized institutions and professional communities is of great importance. In this context, the documents of the American Institute of Electrical and Electronics Engineers (hereinafter – IEEE), which address almost all aspects of the development, implementation and use of AI (see, for example, the Standard on Data and AI Literacy, Skills and Readiness № P7015 dated 23.09.2021 and the Standard Process Model for Addressing Ethical Issues in System Design № IEEE 7000-2021 dated 30.06.2016), deserve attention[265]. Documents of specialized organizations already currently contain a list of recommendations for developers, possible threats to the use of AI, and measures to improve the qualifications of persons involved in AI relationships[266]. The normative provisions enshrined in these documents have been developed by experts precisely for the purpose of ensuring the safety of AI-developments, in connection with which they can be used as a basis for the system of international standards in the field of intellectual developments.

In the field of medicine, the principle of safety of using AI has its own specificity, since medical intervention is closely connected with causing harm to a human being. The difference between intervention and harm is the achievement of legitimate goals (preventive, research, diagnostic, therapeutic or rehabilitative) within the framework of established health care delivery procedures. However, even failure to achieve the objectives in some cases does not make the intervention illegal, as it is a priori associated with a natural risk of harm. Therefore, the procedure for obtaining informed consent from the patient and the proper implementation of the principle of risk management are of great importance.

An important element of the principle of safe use of AI is the introduction of a special procedure that some researchers call «algorithm ethics verification»[267]. This procedure consists in checking the safety of the behavior of an intelligent system in a number of ambiguous, specially modeled situations. In our opinion, the algorithm, at least, should include rules for determining such ambiguous situations, since their solution itself can be transferred to a human being (a specialist or the patient). For this reason, the provision of high-tech medical care is often associated with the requirement of individualized supervision and the prohibition to refuse it in cases where the intervention may have significant consequences for the patient's health (Art. 7 of the Additional Protocol to the Oviedo Convention of 1997 of 27.11.2008).

The relationship between the principle of safe use of AI and the other principles identified in this paragraph is clear: increasing the transparency of an algorithm improves its safety, in order to obtain

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[265] AIS Standards [Electronic resource]: Artificial Intelligence Systems Standards of IEEE Standards Association // IEEE SA: [website]. URL: https://standards.ieee.org/initiatives/artificial-intelligence-systems/standards/ (date of access: 30.05.2023).

[266] By «participants in AI relations» we mean persons who are connected with the development, admission to use, production, introduction into civil circulation, transportation, storage, sale, operation, maintenance and decommissioning of AI systems; persons who participate in the cross-border exchange of intellectual technologies, methodologies and data; participants in relations to ensure the safe use of AI in the provision of medical care and data processing.

[267] Zhuravleva A.V. Op. cit. P. 151-152.

informed consent the subject needs to communicate all potential threats to its safety, while systems with an unacceptable risk of harm will generally not be allowed to circulate. This relationship indicates, first, the existence of a set of formally defined rules that constitute the basis for legal regulation of AI (or, at least, the need for their legal regulation); second, the formation of such principles of a system, the proper implementation of which will ensure the development and use of predictable and safe AI.

2.2.3. Risk management principle

The principle of risk management is often mentioned in specialized sources of international law and official documents on AI, but its content is not sufficiently defined. We believe that the said principle is an independent normative provision, which is of great importance for the whole AI-industry due to the following.

The principle of risk management has found its most detailed disclosure in the UNESCO Recommendation on the Ethical Aspects of AI of 2021. Based on the analysis of a number of provisions of the Recommendation (paragraphs 25, 27, 39, 50, 53, 64 and 133), we can conclude that the content of the principle is disclosed through several directions:

1. assessment of security risks through monitoring of possible threats of harm to protected human values, rights and legitimate interests. At the same time, it is supposed to assess risks both on an individual scale in relation to a specific AI system and more globally – as a forecast of socio-economic, ethical, legal and other threats associated with the introduction of a certain technology. Risk assessment should also be carried out taking into account the learnability of algorithms, therefore, threat monitoring should be constant;

2. risk assessment of the security of AI systems, which includes the study of vulnerabilities of the algorithms themselves and the information networks associated with their functioning to unauthorized access, hacking or other external interference;

3. taking measures to minimize risks. Risk assessment should not be a goal in itself – the forecast of potential threats should be accompanied by the implementation of a set of measures aimed at eliminating or minimizing the identified risks. The implementation of the risk management principle in this part has serious practical consequences in the form of requirements for the development, introduction into civil circulation and operation of algorithms (to be discussed in § 3.3 of the dissertation).

The study of EU Resolution № 2015/2103 allows to derive an additional component of the risk management principle, which is the acceptance of risks on the basis of consent. Identifying the risks of the development and use of the technology will allow for the proper allocation of areas of responsibility among the participants in the AI relationship, who will be able to accept such risks on the basis of informed consent. This component is an integral part of an effective tort liability mechanism (§ 3.4 of the

dissertation). According to the European Parliament, the principle of risk management may become an alternative to the principle of objective liability.

Finally, according to the draft EU Regulation on harmonized rules on AI of 16.05.2023, the results of the assessment of potential risks of AI systems influence the scope of obligations of their producers and users. Equally important, the draft Regulation contains a prohibition on the use of algorithms with an unacceptable level of risk to human safety, which include, inter alia, systems that use subconscious or purposeful methods to manipulate or target human vulnerability, or algorithms designed to socially assess people (i.e., classify them based on behavior, socioeconomic status, personal characteristics). In turn, intelligent medical systems are categorized as «high-risk AI», which entails increased quality control of such algorithms, their mandatory registration, special requirements for the handling of personal data, stricter technical requirements, as well as requirements for traceability, transparency, oversight, accuracy and reliability of the systems[268].

In our opinion, this principle should apply to the stage of development of medical AI systems. The regulatory framework for risk management at the stage of AI research is laid down in the Additional Protocol to the 1997 Oviedo Convention of 25.01.2005 (CETS № 195). According to this act, when conducting biomedical research, among other things, risk and inconvenience must be minimized. In particular, for research participants, all reasonable measures must be taken to ensure their safety and the intervention itself may, at best, result in a very small and temporary adverse effect on human health. In addition, all research must be conducted only under the qualified supervision of a medical professional while maintaining scientific quality, i.e. the research must be scientifically sound, meet generally accepted criteria for scientific quality, and be conducted in accordance with professional requirements and standards.

However, the Additional Protocol to the 1997 Oviedo Convention of 25.01.2005 (CETS № 195) addresses the issue of research only partially by imposing requirements on scientific projects that involve intervention in the human body (biomedical research on human subjects). However, AI developments may not involve such interference: many algorithms are created exclusively in the laboratory by processing Big Data. At the same time, we cannot leave AI research without legal control. In the apt remark of S.M. Omoundro, «even artificial intelligence with the ability to play chess can be dangerous if not properly designed»[269]. Increased attention should be paid to AI developments for medical applications, as all unforeseen risks of technology development, as well as the deliberate creation of unguided intelligent systems, can cause irreparable harm to life and health.

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[268] Proposal for a regulation of the European Parliament and of the Council on harmonised rules on Artificial Intelligence (Artificial Intelligence Act). P. 10-15, 52, 117-120, 126.

[269] Omohundro S.M. The Basic AI Drives [Electronic resource] / S.M. Omohundro // Frontiers in Artificial Intelligence and Applications. 2008. Vol. 171. P. 483. URL: https://www.gwern.net/docs/ai/2008-omohundro.pdf (date of access: 30.05.2023).

Despite its importance, AI research is not currently the subject of legal regulation. We can find only one document containing general ethical rules for the realization of scientific projects in this field – the mentioned Azilomar AI Principles of 2017, which, nevertheless, are exclusively ethical in nature. At the same time, however, this document contains a disclaimer against the development of unguided AI systems, a provision whose validity we can hardly doubt. The implementation of such a waiver will prevent the targeted development of algorithms designed to violate human rights and freedoms, harm human life and health. This normative provision is formally defined, ensures public interest in the creation of safe and controllable AI, in this regard, it should receive legal formalization.

The principle of risk management is interrelated with the other legal principles of AI regulation. In particular, the existence of a serious risk of human rights violations should entail increased requirements for the transparency of the relevant algorithm, up to and including disclosure of its source code and the data sets used, as well as increased monitoring of such risks. This approach is reflected in paragraph 39 of the UNESCO Recommendation on the Ethical Aspects of AI of 2021, the draft EU Regulation on Harmonized Rules on AI of 16.05.2023, and the OECD Council Recommendation on AI of 2019 (para. 1.4).

In order to effectively implement the principle of risk management, a special procedure should be established at the international level (1) to forecast and monitor the risks of the development and use of AI developments, and (2) a system of competent authorities should be established to implement or supervise such procedures.

2.2.4. Transparency principle

The principle of transparency, which some researchers refer to as an element of the human right to information[270], we propose to consider as one of the basic legal principles of international legal regulation of AI. This principle aims to ensure the explainability of algorithms, the lack of which is one of the key problems in creating specific legal regulation of technology.

Thus, AI is a technically complex product based on architecture and operating principles that are difficult to understand by a non-specialist. The regularities discovered by an algorithm in the learning process may not be known to a human being[271]. The opacity of the decision-making mechanism generates the problem of inexplicability of the results obtained by AI, and also reduces the interpretability of

[270] Malyshkin A.V. Op. cit. P. 454.
[271] Meldo A.A. Op. cit. P. 10.

algorithms[272] (the so-called «black box» problem[273]). At the same time, developers of AI systems are not always in close contact with users, which prevents prompt consultation.

This is the main difference between traditional and innovative ways of providing medical care. The physician is able to explain his/her actions and decisions[274] and is responsible for them[275], which makes the traditional approach more acceptable to patients, at least from a psychological point of view. On the other hand, to the detriment of its interpretability, AI is capable of producing more accurate clinical decisions (diagnosis or treatment) when properly applied – this factor can also be decisive in the patient's or professional's choice of medical intervention.

Equally important, problems in explaining AI results arise from medical professionals themselves, who also lack a clear understanding of how the algorithms work. Performing the functions of an AI system operator, a medical worker is limited by the ability to load input data and set certain settings, but the mechanism and methods of decision-making are initially embedded in the program by the developers and remain beyond the control of the doctor[276]. Professional medical training will be able to distinguish between incorrect clinical decisions made by an algorithm, however, in non-obvious cases, the ability to critically evaluate the algorithm's results is virtually non-existent among physicians.

Pre-production by developers of a «decision tree» that a system can arrive at is not applicable to AI, which is capable of self-learning, building its own logic chains and identifying patterns[277]. The presented way of solving the problem (the so-called «white box» model[278]) is most appropriate for expert systems[279], which were technological predecessors of AI and functioned within a clearly defined set of scenarios: examples of such systems are the programs DXplain[280] and MYCIN[281]. However, expert systems are markedly inferior in efficiency to machine learning-based algorithms or deep neural network architecture[282]. In this connection, the normatively enshrined requirement to develop AI exclusively

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[272] Ching T. Op. cit.

[273] Ivshin A.A. Op. cit. P. 136; Carter M.S. Op. cit. P. 26; Antoniades Ch. The Year in Cardiovascular Medicine, 2020: digital health and innovation / Ch. Antoniades, F.W. Asselbergs, P. Vardas // Russian Journal of Cardiology. 2021. № 26 (3). P. 122.

[274] Kamensky S. Artificial Intelligence and Technology in Health Care: Overview and Possible Legal Implications / S. Kamensky // DePaul journal of health care law. 2020. Vol. 21. № 3. P. 3.

[275] Ivanova A.P. Op. cit. P. 153; Kamensky S. Op. cit. P. 3.

[276] What do we need to build explainable AI systems for the medical domain? [Electronic resource] / A. Holzinger [et al.] // ARXIV.ORG: A free distribution service and an open-access archive. arXiv:1712.09923v1 [cs.AI]. 2017. URL: https://arxiv.org/pdf/1712.09923.pdf (date of access: 30.05.2023).

[277] Kiseleva A.Y. Application of artificial intelligence in health care: aspects of medical law / A.Y. Kiseleva // Medical Law: Theory and Practice. 2020. Vol. 6. № 2 (12). P. 31.

[278] Ivshin A.A. Op. cit. P. 135.

[279] Meldo A.A. Op. cit. P. 10.

[280] Using decision support to help explain clinical manifestations of disease [Electronic resource] // MGHLCS.ORG: official website of The Laboratory of Computer Science at Massachusetts General Hospital. [2017]. URL: http://www.mghlcs.org/projects/dxplain (date of access: 30.05.2023).

[281] Computer-based consultations in clinical therapeutics: explanation and rule acquisition capabilities of the MYCIN system / E.H. Shortliffe [et al.] // Computers and biomedical research. 1975. Vol. 8. №. 4. P. 303-320.

[282] Meldo A.A. Op. cit. P. 15.

according to the «decision tree» method is also not a way to solve the problem, as it will significantly reduce the efficiency of technical solutions.

The practical consequence of this problem is the unpredictability of actions and decisions made by AI, which prevents quality control of the algorithm and leads to the risk of making unreliable clinical decisions that can cause harm to human life and health. In addition, the non-transparency of algorithms complicates the implementation of other legal procedures applicable to relations complicated by AI, such as: obtaining informed consent for medical intervention or personal data processing, bringing to tort liability, etc. For this reason, the development of models of «explanatory intelligence» is currently attracting increasing scientific interest[283].

The importance of AI transparency is evidenced by the attention the issue is receiving at the interstate level. We can find the requirement to ensure transparency of algorithms in almost every international legal act devoted to AI (see below), as well as in domestic acts (see paragraph «c» of clause 19 of the National AI Development Strategy for the period until 2030) and normative documents of non-state international organizations (for example, in the WMA Statement on Augmented Intelligence in Medical Care of 2019).

The 2021 UNESCO Recommendation on the Ethical Aspects of AI considers transparency as an indispensable condition for the effective implementation of the liability mechanism (para. 37). It is noted that the principle of transparency is aimed at ensuring that the algorithm's decision-making process is understandable and that explanations of the results obtained with the help of AI are provided, including accessibility for understanding the algorithm's behavior, its input data and their impact on the result (para. 40). Similarly, the principles of transparency and explainability are enshrined in para. 1.3 and subpara. «b» para. 1.4 of the OECD AI Council Recommendation of 22.05.2019[284]. Due to the extensive regulation of similar provisions in international documents, we propose to consider them as the content of the principle of transparency.

The principle of transparency is also emphasized in the Code of Ethics for Robotics Developers, which is an Annex to EU Regulation № 2015/2103. In particular, the principle of transparency is implemented in two areas[285]:

1. organizational, in the framework of which the developers are obliged to provide access to all interested parties to the necessary information, including information about possible dangers of the technology for society or the environment, as well as the obligation to provide an opportunity to participate

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[283] Meldo A.A. Op. cit. P. 15.

[284] Recommendation of the OECD Council on Artificial Intelligence of 22.05.2019 № OECD/LEGAL/0449 [Electronic resource] // OECD Legal Instruments: [website]. URL: https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449 (date of access: 30.05.2023).

[285] Nikitenko S.V. Transparency principle… P. 39.

in the decision-making procedure of the algorithm, usually through changing input data, hyperparameters, suspension or complete termination of the program operation;

2. technical, in the framework of which the principle of transparency stipulates the need to provide access to the source code, input data and information on AI design features to interested parties (the circle of which is not normatively defined) in case of harm, which will allow to establish their causes of incidents. In our opinion, the range of such persons should be determined by the tasks set: for compensation of the harm caused, such persons are the victim, the harm causer, the expert and the authorized official or jurisdictional authority, while for prevention of incidents in the future, the interested persons are the representative of the manufacturer, the service organization and the authorized supervisory body in the field of application of the algorithm.

The principle of transparency is manifested in special legal procedures for obtaining consent to the processing of personal data and medical intervention. The analysis of special regulation in this area shows that the principle of transparency also implies: (1) provision of information about the data processed by the AI system, the logical scheme of decision-making by the algorithm, as well as persons who have access to the system, possible results, risks and significance (impact on the subject) of the decisions made; (2) understandability and accessibility of the form and content of such information.

In our view, transparency requirements should differ depending on (1) the scope of the AI, (2) the qualifications of the interested party, and (3) the right secured[286]. It seems logical that for a patient with no specialized knowledge, information about algorithm operation should be presented in a simplified form, while a physician should be provided with an «extended» version of the report using professional terminology for a more complete evaluation of the system's solutions. In this context, a balance must be struck between form and content, otherwise we run the risk of encountering the so-called «paradox of transparency», according to which oversimplification of material inevitably leads to generalization and loss of information[287].

Additionally, in our opinion, it should be ensured that relevant AI performance indicators (so-called metrics) are made available at any time and to any person and should be regularly updated. In particular, it is advisable to include in the algorithm a function to display all relevant metrics (including sensitivity, specificity and ROC AUC – to be detailed in §3.3 of the dissertation study) updated at the time of the query. Providing this information will ensure transparency of AI for both the patient and the medical professional. For the patient, the provision of information on the effectiveness of AI is key to the decision to intervene with AI.

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[286] Nikitenko S.V. Transparency principle… P. 40.

[287] Richards N.M. Three Paradoxes of Big Data / N.M. Richards, J. King // Stanford Law Review Online. 2013. № 66. P. 42-43.

An important aspect of the AI transparency principle is to ensure traceability of the source of the algorithm's training data, which is also emphasized by some researchers[288]. As noted by experts in the WMA's 2019 Statement on Augmented Intelligence in Medical Care, realizing such a capability is critical to understanding the risk associated with the use of medical AI systems in the delivery of care to individuals whose individual characteristics differ significantly from those in the training dataset.

Finally, it is necessary to take into account one of the objective regularities of intellectual technologies, which we have outlined earlier: the existence of an inverse relationship between the degree of predetermination of algorithm decisions, its predictability on the one hand, and the efficiency of the system on the other. The AI legal regime should be based on an effective combination of explainable algorithms (for example, the already mentioned «decision tree») and deep machine learning methods[289]. Establishing a proper balance between these technological extremes is the main task facing IT specialists. Its solution can directly affect the current state of AI development and the efficiency of its application in vital areas of activity.

The analysis of existing sources of international and integration law, as well as the existing doctrinal positions, allows us to consider explainability as the main element of the legal regime of AI, and the corresponding principle of transparency as one of the key principles of legal regulation of AI in general. As the researchers note, the future fate of the technology itself actually depends on the effectiveness of the implementation of the principle of transparency[290]. At the same time, the legislator has yet to develop a set of measures aimed at ensuring the accessibility of information processes processed by AI, as well as to determine the form and scope of providing information on the work of AI to interested parties.

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[288] Cohen G. Informed Consent and Medical Artificial Intelligence: What to Tell the Patient? / G. Cohen // Georgetown Law Journal. 2020. Vol. 108. P. 1467-1469.

[289] Ivshin A.A. Op. cit. P. 135.

[290] Vasiliev A.A. The term «artificial intelligence» in Russian law: doctrinal analysis. P. 43; Ponkin I.V. Op. cit. P. 94-95; Morhat P.M. Artificial intelligence: a legal perspective. P. 69; Malyshkin A.V. Op. cit. P. 446.

CHAPTER 3. SPECIAL INTERNATIONAL LEGAL REGULATION OF CONDITIONS FOR THE USE OF ARTIFICIAL INTELLIGENCE TECHNOLOGIES IN MEDICAL PRACTICE

§ 3.1. Medical intervention using artificial intelligence

Active use of AI in healthcare contributes to a more effective realization of the constitutional human right to health protection (Art. 41 of the Constitution of the Russian Federation[291]) y improving the quality and accessibility (including financial) of medical care[292]. However, without adapting the procedure for obtaining informed voluntary consent to medical intervention to modern technologies, the positive effect may be offset by the increased risk of harm to the health of patients.

The use of AI systems in medical intervention makes it difficult to implement a consent mechanism due to the opacity of the algorithm's decision-making mechanism. The main problem is to provide the patient, who has no specialized knowledge, with information in an accessible form about the AI decision-making process. The problem arises as to how much information to provide to the patient: whether it is sufficient to simply mention the use of the algorithm in the intervention process or whether it is necessary to describe the principles of its operation[293]? To answer this question, the purpose of consent to medical intervention and the rights and legitimate interests of the patient should be examined.

Analysis of the sources of national and international law (which will be cited below) shows that obtaining informed voluntary consent is a prerequisite for medical intervention. Some researchers consider such consent to be central to the ethical principle of patient autonomy[294], the essence of which is to give patients the freedom to choose their medical intervention (including complete refusal) and to make final decisions about their own health status[295]. Despite the ambiguous assessment of patient autonomy as an ethical and even more so as a legal principle, most experts note the need to provide the patient with full and accessible information about the upcoming intervention[296], which indicates the importance of the problem of the scope of information provision in the use of AI technologies.

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[291] Constitution of the Russian Federation: adopted by popular vote on 12.12.1993 with amendments approved during the all-Russian voting on 01.07.2020 [Electronic resource]. URL: http://pravo.gov.ru/constitution/ (date of access: 30.05.2023).

[292] Privalov S.A. Artificial intelligence technologies in the sphere of ensuring the right to health protection, affordable and quality medical care: prospects and problems of regulation / S.A. Privalov // Vestnik of SSCSA. 2021. № 4 (141). P. 36; Artificial Intelligence and Machine Learning in Radiology: Opportunities, Challenges, Pitfalls, and Criteria for Success / J.H. Thrall [et al.] // Journal of the American College of Radiology. 2018. Vol. 15. № 3. P. 504-508.

[293] Kiseleva A.Y. Op. cit. P. 31.

[294] Ibid. P. 30; Rendtorff J.D. Basic ethical principles in European bioethics and biolaw: Autonomy, dignity, integrity and vulnerability – towards a foundation of bioethics and biolaw / J.D. Rendtorff // Medicine Health Care and Philosophy. 2002. № 5. P. 236-238.

[295] Bakhin S.V. Forced medical measures and human rights. P. 33.

[296] Barbashina E.V. The principle of patient autonomy: possible and actual / E.V. Barbashina // Bulletin of Tomsk State University. 2019. № 449. P. 66-68.

In Russia, the issue of obtaining consent to intervention is regulated by Federal Law № 323-FZ «On Fundamentals of Health Protection of Citizens in the Russian Federation» dated 21.11.2011[297] (hereinafter – Law № 323-FZ), according to part 1 of Article 20 of which informed voluntary consent of a citizen to medical intervention is a necessary precondition for such intervention and must be given (1) voluntarily (2) based on information provided by the health care provider (3) in an accessible manner (4) complete information (5) about the goals, methods of health care delivery, associated risks, (6) possible options for medical intervention, its consequences, and (7) the expected outcomes of health care delivery. The consequences of refusing to give consent must also be explained to the person in an accessible form (part 4 of Art. 20 of Law № 323-FZ).

The obligation to obtain consent in the Russian Federation is established only for certain types of medical interventions. Thus, the Order of the Ministry of Health and Social Development of the Russian Federation from 23.04.2012 № 390n[298] approved the List of certain types of medical interventions for which citizens give informed voluntary consent when choosing a doctor and medical organization for primary health care. However, the use cases of AI systems (as a separate intervention or as part of an intervention) are not specified in this List. In this regard, Russian legislation does not currently enshrine the obligation to obtain patient consent for the use of algorithms in interventions. Moreover, we will not find a special procedure for consent to the use of AI in interventions in the legislation of developed countries either. Many researchers note that this issue is poorly studied, limiting themselves to mentioning a number of problematic issues that require legal regulation (e.g., disclosure to the patient of the ethnic and/or racial composition of the training dataset[299]).

The Universal Declaration on Bioethics and Human Rights, adopted on 19.10.2005 by the General Conference of UNESCO[300], being an international instrument of recommendatory nature, in Art. 6 enshrines the requirement to obtain consent to medical intervention for preventive, diagnostic or therapeutic purposes, which must be, among other things, informed, which implies the provision of relevant information about the intervention in an adequate and understandable form. According to paragraph 2 of this article, the mechanism of obtaining consent was also extended to scientific research, which demonstrates the need for legal regulation of this type of intervention. In this context, it should be noted that the prohibition on conducting medical or scientific experiments without the free consent of the person is established in the International Covenant on Civil and Political Rights of 1966 (Art. 7).

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[297] On the basis of health protection of citizens in the Russian Federation : Federal Law of 21.11.2011 № 323-FZ, ed. of 02.07.2021 // CL RF. 2011. № 48. Art. 6724.

[298] On Approval of the List of certain types of medical interventions for which citizens give informed voluntary consent when choosing a doctor and medical organization to receive primary health care : Order of the Ministry of Health and Social Development of Russia from 23.04.2012 № 390n // Rossiyskaya Gazeta. 2012. № 109.

[299] Cohen G. Informed Consent and Medical Artificial Intelligence: What to Tell the Patient? / G. Cohen // Georgetown Law Journal. 2020. Vol. 108. P. 1467-1469.

[300] Universal Declaration on Bioethics and Human Rights of 19.10.2005 [Electronic resource] // UN: [website]. URL: https://www.un.org/ru/documents/decl_conv/declarations/bioethics_and_hr.shtml (date of access: 30.05.2023).

The procedure for obtaining informed voluntary consent is also enshrined in the 1997 Oviedo Convention, Art. 5 of which states the general rule: a medical intervention may be carried out only after the person who has been given information about the purpose, nature of the consequences and risks of the intervention has given his or her voluntary informed consent. Russia has neither signed nor ratified the 1997 Oviedo Convention, but the procedure for obtaining informed voluntary consent enshrined in Art. 20 of Law № 323-FZ not only includes all the conditions listed in Art. 5 of the 1997 Oviedo Convention, but is generally more elaborate.

The Additional Protocol to the Oviedo Convention of 1997 of 25.01.2005 (CETS № 195), unlike the mentioned Universal Declaration on Bioethics and Human Rights of 2005, regulates in detail the procedure of obtaining consent for the participation of a person in biomedical research. The specifics of obtaining consent in this case is the need to provide the participant with information about the ethical acceptability of the research (opinion of the competent authority), about mechanisms for protecting his rights in case of adverse effects, as well as about the benefits of the potential results of the research project.

Analysis of these legal acts shows that the issue of the specifics of providing informed voluntary consent for medical intervention using AI is not regulated. Challenges remain due to the low interpretability of intelligent systems and the consequent difficulty in providing adequate, complete information in an accessible form about an upcoming intervention. For this reason, given the direct correlation between informed voluntary consent and the patient's health status and the observance of his/her rights and legitimate interests, international legal regulation of a special procedure for obtaining consent in cases of AI interventions is required. The relevant procedure should include the following measures:

1. ensuring transparency of the algorithm's decision-making process, including the obligation to provide up-to-date metrics as a demonstrable measure of its effectiveness[301];

2. providing full information about the purpose, effects of the intervention and the likelihood of complications. Different predictions should be provided depending on the intervention modality (with or without AI), so that the patient is able to evaluate for themselves the effect of using intelligent technology in the intervention process;

3. informing the patient about the results of diagnosis and previous treatment, which will allow to form a full understanding of the history of the disease (its progression) and the potential effectiveness of the proposed intervention[302].

[301] Kiseleva A.Y. Op. cit. P. 30.
[302] Ibid.

At the moment, the most obvious and reasonable measure that requires legal regulation is the inclusion in the informed consent of an indication of the use of algorithms in the implementation of a particular medical intervention. This proposal is also supported by domestic researchers[303].

An important element of the procedure under consideration is the clear establishment of cases in which medical intervention is allowed without the consent of the patient. Such exceptions are currently set out in international legal acts and can be conditionally divided by the purpose of the intervention into restrictions aimed at (1) protecting the health of the patient – group 1, and (2) ensuring public safety and public health – group 2.

Analysis of Art. 6-9 of the Oviedo Convention of 1997, Art. 10-12 and 14 of the Additional Protocol to the Oviedo Convention of 1997 of 27.11.2008 allows to deduce the following exceptions of the 1st group, when consent is not required in order to protect the health of the patient:

— if the person is incapacitated (due to age or has been recognized as such), the consent of his/her legal representative must be obtained, provided that such person is ensured to participate in the consent procedure to the best of his/her ability.;

— if the person has legal capacity but suffers from a mental disorder that prevents consent, intervention shall be carried out only when the absence of intervention is likely to cause serious harm to the health of such person, subject to safeguards to protect his/her rights (ensuring surveillance, monitoring and appeal procedures);

— if the person is legally capable and mentally healthy, medical intervention without consent is only possible in the case of an emergency, provided that appropriate consent cannot be obtained, the intervention is necessary to improve the state of his or her health and must be carried out without delay.

This takes into account the patient's previous behavior and wishes, as well as the proportionality between the possible benefits of an uncoordinated intervention and the risks of negative consequences of not providing timely care. In biomedical research, it must be further established that the participation of a particular individual in a research project furthers the objectives of the research more effectively than the participation of others capable of giving consent.

Group 2 exceptions are regulated by Art. 26 of the 1997 Oviedo Convention, according to which it is allowed to intervene in the field of health protection, provided that the relevant restrictions are provided by law and are necessary in a democratic society in the interests of public safety, for the prevention of crime, the protection of public health or the protection of the rights and freedoms of others. These rules in general are a universal criterion of admissibility of any interference in human rights and freedoms, which is reflected in para. 2 of Art. 29 of the Universal Declaration of Human Rights of 1948. In this context, the use of coercive measures in the field of health care may also be due to a threat to

[303] Kovelina T.A. Toward the question of legal regulation of the use of artificial intelligence in medicine / T.A. Kovelina, A.V. Sobyanin, V.M. Marukho // Humanities, Socio-Economic and Social Sciences. 2022. № 2. P. 150.

public safety and health. In particular, compulsory medical measures may be applied to prevent the spread of particularly dangerous infectious diseases (quarantine of the sick, implementation of compulsory preventive measures, etc.), which is reflected in the 2005 International Health Regulations. Compulsory medical measures are also used to combat venereal diseases (forced examination, compulsory treatment), prostitution (registration, forced medical examination, forced treatment), chronic alcoholism and drug addiction[304]. We discussed this issue in more detail in § 1.1 of the dissertation.

We believe that the international legal regulation in terms of exceptions to the general rule on the need to obtain informed voluntary consent for medical intervention is well developed and does not require amendment. At the same time, we note that cases of medical intervention without the patient's consent should be considered as a measure of last resort. Currently, there is a need for international legal regulation of a set of measures to ensure the effective right of the patient to provide informed consent in medical intervention with the use of AI, including through the enshrinement of our proposed recommendations in international legal acts.

[304] Bakhin S.V. Forced medical measures and human rights. P. 34.

§ 3.2. Confidentiality of health data

The functioning of AI is directly related to the processing of a large amount of information. AI training requires voluminous datasets consisting of thousands of medical data samples – X-rays, tomograms, gene sets, pathology descriptions, etc. For the algorithm to work, it is critical to ensure the completeness of information about the patient's health status and therapy results, which naturally leads to the trend towards continuous monitoring of human health. The development of the Internet of Medical Things (IoMT) makes it possible to technically realize the mechanism of round-the-clock collection of medical data, their automatic processing and clinical decision-making. In addition, as experts note, machine learning algorithms can identify a person by individual fragments of information among large datasets, which calls into question the effectiveness of existing methods of anonymizing personal data[305]. Modern information technology thus increases the risk of a breach of personal data privacy[306].

In order to protect personal data in case of their automated processing, many researchers propose to regulate the procedure and conditions for access, processing and storage of data on patients' health status, which are contained in databases[307]. In scientific works devoted to this problem, there is a widespread position on the «special status» of clinical data, as well as the need to develop their special legal regime[308]. States also pay considerable attention to data privacy (e.g. in WHO's Draft Global Digital Health Strategy 2020-2050, WHO Resolution WHA58.28 on E-Health, or the Oviedo Convention of 1997), and para. 39 of the National AI Strategy 2030 specifically mentions the need for a legal and regulatory framework to ensure data protection.

At the same time, at the moment, a number of international and integration law acts are already in force, which regulate in detail the procedure of personal data processing with the use of modern technologies. A legitimate question arises about the validity of the proposals on the need to improve the legal regime of personal data in order to enhance their protection. In order to answer this question, we should examine the current legal regulation in the field of confidentiality of personal data, including information on patients' health.

First of all, let us consider the concept of personal data. Due to the absence of other sources of international law at the universal level, which would enshrine international obligations in the field of personal data protection, we have to refer to regional sources, namely the Council of Europe Convention

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[305] See: WMA Statement on augmented intelligence in medical care. URL: https://www.wma.net/policies-post/wma-statement-on-augmented-intelligence-in-medical-care/ (date of access: 30.05.2023).

[306] Antoniades Ch. Op. cit. P. 122; Gorodov O.A. Main directions of improvement of legal regulation in the sphere of digital economy in Russia / O.A. Gorodov, M.A. Egorova // Law and Digital Economy. 2018. № 1. P. 8.

[307] Chelysheva N.Y. Op. cit. P. 19.

[308] Health care in Russia [Electronic resource]: statistical collection / Federal State Statistics Service of the Russian Federation. Moscow, 2017. URL: https://rosstat.gov.ru/folder/210/document/13218 (date of access: 30.05.2023).

for the Protection of Individuals with regard to Automatic Processing of Personal Data of 1981[309] (hereinafter – Convention ETS № 108), the «regional specificity» of which and the special approach of European institutions to issues of this kind cannot be overlooked. Thus, according to Art. 2 of the ETS Convention № 108, personal data means any information about a defined or identifiable natural person. At the same time, Art. 6 of the Convention identifies special categories of data, including data on human health, which cannot be subjected to automated processing unless domestic legislation establishes safeguards to protect the rights of the data subject.

The said list of special categories of personal data has been extended in the Protocol to the Convention ETS № 108 of 10.10.2018 (hereinafter Protocol CETS № 223)[310], which is generally dedicated to ensuring data privacy due to the emergence of automatic processing technologies. In particular, genetic data are recognized as a special category of personal data under this Protocol. We find a similar provision in the Recommendation of the Committee of Ministers of the Council of Europe № CM/Rec(2019)2 of 27.03.2019[311]. However, the Regulation № 2016/679 of the European Parliament and of the Council of the EU «On the protection of natural persons with regard to the processing of personal data ... (General Data Protection Regulation)»[312] (hereinafter – Regulation № 2016/679, GDPR), which is one of the most elaborated legal acts in the field of personal data protection, is of the greatest interest.

The concept of personal data in the GDPR includes information on physical and genetic identity traits that make it possible to identify an individual (Art. 4); «health-related data» means personal data that relate to the physical or mental health of an individual, including information on the provision of medical services that disclose information on health conditions. In its turn, according to Art. 9 of Regulation № 2016/679, genetic and health-related data belong to a special category of personal data, the processing of which is subject to stricter requirements related to the adoption of additional organizational and technical measures ensuring enhanced security of such data (we will discuss them further).

The processing of personal data by intelligent algorithms itself falls under the general concept of «processing of personal data» without any modification. Moreover, the Convention ETS № 108 explicitly states that processing includes the performance of logical and/or arithmetical operations on data.

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[309] Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28.01.1981, ETS № 108 // CL RF. 2014. № 5. Art. 419.

[310] Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 10.10.2018, CETS № 223 [Electronic resource] // Council of Europe: [website]. URL: https://rm.coe.int/16808ac918 (date of access: 30.05.2023).

[311] On the protection of health-related data: Recommendation adopted by the Committee of Ministers of the Council of Europe on 27.03.2019 № CM/Rec(2019)2 [Electronic resource] // Council of Europe: [website]. URL: https://edoc.coe.int/en/international-law/7969-protection-of-health-related-date-recommendation-cmrec20192.html (date of access: 30.05.2023).

[312] Regulation (EU) № 2016/679 of 27.04.2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive № 95/46/EC (General Data Protection Regulation) // Offic. J. of the Europ. Union. Ser. L. 2016. Vol. 59, L119. P. 1-88.

Thus, it is not necessary to expand the concept of personal data and their processing. Therefore, let's proceed to the consideration of the procedure of personal data processing and identify the existing risks of confidentiality breach in connection with the use of intelligent systems.

The specificity of data processing by algorithms lies in the implementation of this process automatically, without human participation, which raises the issues of (1) the legal regime of personal data processing by intelligent programs, (2) the legal status of the decisions taken based on the results of such processing, (3) ensuring protection measures for the AI system itself (including databases) and (4) providing personal data subjects with guarantees to respect their rights. First of all, it should be noted that the processing of data without human intervention is already regulated in the sources of law and is generally referred to as «automated processing» (for example, in Art. 2 of the Convention ETS № 108). In turn, many provisions of the GDPR also deal with the specifics of automated processing of personal data.

Thus, according to the GDPR, making decisions that may entail legal consequences for a person (granting a right, arising an obligation, etc.) or have a significant impact on him/her, on the basis of automated processing of special categories of personal data is allowed only in two cases: with the consent of the subject or due to the need to ensure the «special public interest» (protection of the constitutional order, health, rights and legitimate interests of others, ensuring the security of the state, etc.) of such processing (para. 4 of Art. 22 of the GDPR). A similar rule is contained in Protocol CETS № 223, but with one difference: it is prohibited, without the subject's consent, to make automated decisions that may have a material adverse effect on the subject (without a public interest clause). In our opinion, the reference to the negative nature of the impact in Protocol CETS № 223 is evaluative and raises questions (1) about what impact to recognize as negative and (2) about the entity that should make such an assessment. We believe the approach set out in the GDPR is more consistent as it gives the subject more control over their personal data and how it is processed.

In turn, ensuring the control of the data subject over his/her data constitutes the essence of the principle of personal autonomy of the personal data subject provided for by the Convention ETS № 108. «Control» rights of the data subject involve the ability to (1) know of the existence of an automated personal data file, its purposes, and the name and location of the file operator; (2) obtain, within a reasonable time and without undue expense, confirmation of whether the data concerning him or her are stored in an automated file and to obtain such data in an intelligible form; and (3) seek rectification or erasure of the data if they have been subjected to irregularities.

Despite the rational basis for granting personal data subjects these rights, their practical realization may be significantly hampered due to the intensive data exchange between information systems, as

well as the uncertainty of all the purposes for which automated processing may be carried out[313]. Moreover, some researchers have generally noted that the principle of targeted data processing (or the data minimization principle under Article 5(1)(c) of the GDPR), according to which only data that meets the purposes for which it is processed should be processed, prevents the pooling of databases, which slows down the pace of AI research[314]. These problems will be discussed in more detail below. At this point, it is important for us to understand that the sources of law already establish a special procedure for automated data processing.

The use of AI legitimately raises the question of the form and content of the information provided to the subject regarding the processing procedure for consent. The basic rules for obtaining consent to the processing of personal data are set out in Protocol CETS № 223 and Convention ETS № 108: the subject's consent to the processing of his or her personal data must be free, informed and clear. GDPR contains additional requirements that consent must be voluntary and written (Art. 7). At the same time, the current sources of international law practically do not take into account the specifics of the procedure for obtaining consent to data processing using AI systems. However, in our opinion, this only slightly increases the risk of violation of personal data subject's rights due to the following.

Unlike consent to medical intervention, where the efficiency and properties of the algorithm are among the key factors for the decision to intervene, the «informedness» of consent to data processing does not affect the data processing mechanism itself. It is sufficient to inform the patient about the purpose of processing, data retention period and other general information, which, as a rule, is not related to the decision-making process of the AI system[315]. In this regard, there should be no difficulties in obtaining informed consent in this part: the problem is solved by simply listing information about the processing process and its results according to the list in paragraph 4 of Article 9 of the Federal Law of the Russian Federation «On Personal Data» of 27.07.2006 № 152-FZ[316]. The requirement to provide information on the existence of an automated decision-making process, including information on the logical scheme of the algorithm, as well as the significance and intended consequences of such processing, is separately set out in the GDPR (Article 13(2)(f)). However, it is noted that the relevant information should only give the data subject a general idea of the intended processing, which also supports our position that it is not necessary to disclose to the data subject all details of the algorithm's operation.

At the same time, in the scientific literature we can find authors who note that in the conditions of widespread dissemination of information technologies, the informed voluntary consent to the

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[313] Tschider C.A. Op. cit. P. 441.

[314] Savelyev A.I. Problems of application of legislation on personal data in the era of «Big Data» (Big Data) / A.I. Savelyev // Law. Journal of the Higher School of Economics. 2015. № 1. P. 55.

[315] Savelyev A.I. Scientific and practical article-by-article commentary to the Federal Law «On personal data». [Electronic resource] / A.I. Savelyev. 2nd ed., revision and supplement. M.: Statute, 2021. 468 p. // Reference legal system «ConsultantPlus». Access mode: http://www.consultant.ru/.

[316] On personal data : Federal Law of the Russian Federation of 27.07.2006 № 152-FZ, ed. of 02.07.2021 // CL RF. 2006. № 31 (1 part). Art. 3451.

processing of personal data becomes a fiction[317]. In particular, the subject is not able to foresee all the consequences and risks to which the automated processing of data may lead, therefore, the consent ceases to be informed in essence. We do not agree with this position: providing the subject with all information related to the procedure and results of personal data processing, as well as predicting every risk of confidentiality breach is practically impossible, but such a requirement is not provided for by the sources of law and is not stipulated by the law. At the same time, a person must be given the opportunity to independently dispose of his/her personal data. As follows from Art. 7 and 8 of the Charter of Fundamental Rights of the European Union[318], the right to control of the data subject over his/her personal data (granting access to such data and the possibility to retrieve them at any time) ensures privacy along with the right to non-interference[319].

However, depriving an individual of the right to control his or her personal data simply because of the difficulty of perceiving the information required to provide consent will inevitably lead to the decision being made by another, more «conscious» subject, which has serious negative consequences and creates a risk of abuse. In this regard, to overcome the «fictitiousness» of the procedure for obtaining consent to the processing of personal data using AI will allow a more effective implementation of the principle of transparency and the development of a balanced approach to the definition of cases of personal data processing without consent, which should be considered in more detail. It is the nature and degree of elaboration of such exceptions that largely determines the likelihood of the realization of round-the-clock data collection. In this regard, cases of data processing without the subject's consent should be formulated in an unambiguous manner that does not allow for an expansive interpretation[320].

As a general rule, the processing of special categories of personal data without consent is allowed, provided that it is necessary, proportionate and for the protection of public interests and values, such as: national security, defense, public order, economic and financial interests of the state (Art. 9, para. 2 (a) of the Convention ETS № 108, Art. 9, para. 2 of the GDPR). The interference with privacy must have a specific purpose, the amount of data used must be minimized, and safeguards must be provided to the subject against misuse or transfer of the data. Each intervention must be accompanied by information on the risks to the rights and freedoms of data subjects that may be conferred on such data subjects (Art. 23(2) of the GDPR).

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[317] Savelyev A.I. Op. cit. P. 57-58.

[318] The Charter of Fundamental Rights of the European Union // Offic. J. of the Europ. Comm. Ser. C. 18.12.2000. C364. P. 1-22.

[319] Voynikanis E.A. Inviolability of private life, personal data and responsibility for illegal collection and dissemination of information about private life and personal data: problems of improving the legislation / E.A. Voynikanis, E.O. Mashukova, V.G. Stepanov-Yegiyants // Zakonodatelstvo. 2014. № 12. P. 74-80; Rodota S. Data Protection as a Fundamental Right (Chapter 3) / S. Rodota // Reinventing Data Protection? / S. Gutwirth [et al.]. Dordrecht: Springer, 2009. P. 80.

[320] Gorodov O.A. Main directions of improvement of legal regulation in the sphere of digital economy in Russia. P. 8.

One exception for uncoordinated data processing is of particular interest to us as it relates to the realization of the right to health care. Thus, according to Art. 9(2)(b) of Convention ETS № 108, data processing may be carried out without consent in order to protect the data subject or the rights and freedoms of others. The wording of this provision creates the risk of its broad interpretation: an unlimited range of situations is possible to justify the protection of the interests of the data subject or third parties. This risk is most evident in the field of medicine, where practically any manipulation of health data is carried out within the framework of medical care, which is always connected with the protection of patients' life and health.

On the one hand, this exclusion would address the lack of clinical data[321]. On the other hand, it will give rise to a number of problems, from increasing the risk of data breaches and the imposition of medical services to violating the principle of legal certainty through the systematic violation of the individual's right to privacy. GDPR, regulating a similar exception in Art. 9(2)(c), stipulates a reservation on the objective impossibility of obtaining the subject's consent. Such an additional condition, in our opinion, will significantly reduce the number of cases of uncoordinated data processing, since the operator will have the burden of proving the impossibility of obtaining the subject's consent.

At the same time, the GDPR also contains contradictory provisions. In particular, the Regulation allows the processing of personal data without the subject's consent (1) for medical and preventive purposes, (2) for the purposes of establishing a medical diagnosis, providing medical and medical-social services, provided that the processing is carried out by a person who is professionally engaged in medical activities and is obliged to maintain medical confidentiality (Art. 9(2)(h) of the GDPR). Obviously, this provision calls into question the need to obtain consent to the processing of personal data in any type of medical intervention.

According to the legislator's position, in such a case the rights of the data subject are ensured precisely due to the preservation of medical confidentiality (Art. 9(3) of the GDPR), which is also pointed out by the Russian law enforcer in the Decision of the Constitutional Court of the Russian Federation № 1176-O dated 16.07.2013[322]. The presented approach expresses the unconditional priority of protection of human life and health over privacy, which negates the importance of the procedure for obtaining informed voluntary consent to the processing of health information. In our opinion, this exception creates wide opportunities for abuse and also leads to an unjustified restriction of the human right to privacy. Some authors also note that this exception provides health care organizations with the

[321] Carter M.S. Op. cit. P. 29.

[322] On refusal to accept for consideration the complaint of citizen Kruglov Alexander Gennadyevich about violation of his constitutional rights by paragraph 4 of part 2 of article 10 of the Federal Law «On personal data» [Electronic resource]: definition of the Constitutional Court of the Russian Federation from 16.07.2013 № 1176-O // Reference legal system «ConsultantPlus». Access mode: http://www.consultant.ru/.

ability to process a patient's non-personal health data even after the patient has withdrawn consent[323]. The use of AI can only exacerbate the negative effects of such an imbalance.

In our opinion, this provision is inadmissible regardless of medical confidentiality. The relevant provisions should be amended: either a clause should be included on the objective impossibility of obtaining the subject's consent in each specific case of intervention, or such exception should not be extended to the collection of personal data. Otherwise, the balance between the individual's right to privacy and the protection of his or her health will be disturbed, and the subject's right to exercise control over his or her data (including its disposal) will virtually disappear.

Ensuring the confidentiality of personal data also limits the freedom of scientific research. Implementing the principle of minimization of personal data without any reservations may slow down technological progress, since most of the data on the patient's health status will be destroyed immediately after the provision of medical care. For this reason, the processing of personal data for scientific purposes (including for the development of AI) without the subject's consent is approved by experts, but provided that appropriate measures are in place to protect such data and the process of its processing[324]. International legal regulation also touches upon this issue. Thus, Art. 9(3) of the Convention ETS № 108 states that for the purposes of automated processing of data for scientific research at the domestic level may be established restrictions on the rights of the subject in terms of the rights to obtain information about the storage of their data in the system, to correct and destroy them. The GDPR does allow for restrictions on the right to access data, restriction of data processing and the right to object to data processing (Art. 89(2)).

According to the fair observation of the drafters of Regulation № 2016/679, the full exercise of all the rights of the data subject without any restrictions would make it impossible to achieve the research objectives. Protocol CETS № 223 explicitly states that in the case of further processing (i.e. processing after the original purposes have been achieved) of data for scientific purposes, the principle of purposeful restriction is inferior to ensuring the security of data processing. A similar approach is implemented in the GDPR, according to Article 5(1)(b) of which further processing of data for scientific purposes may not be incompatible with the purposes of the initial processing. The protection of the rights and freedoms of data subjects in such a case shall be ensured by organizational and technical measures for the protection of the rights and freedoms of data subjects.

Scientific research is therefore a sufficient ground for restricting the rights of the data subject. Privacy in this case is ensured by requiring operators to take protection measures appropriate to the purposes of data processing. In our opinion, such restriction of the personal data subject's rights is

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[323] Fokht O.A. Analysis of the adopted amendments to the Federal Law № 152-FZ «On personal data» [Electronic resource] / O.A. Fokht // Physician and information technologies. 2011. № 5. Reference legal system «ConsultantPlus». Access mode: http://www.consultant.ru/.

[324] Carter M.S. Op. cit. P. 30.

justified because it pursues publicly important objectives: stimulating scientific developments and improving healthcare, the achievement of which can lead to significant improvements and scientific breakthroughs in the field of AI. It is noteworthy that the Russian law in this part contains a gap – the rule on the uncoordinated processing of data for scientific purposes does not apply to the processing of special categories of data. Instead of amending Law № 152-FZ «On Personal Data», the legislator allowed uncoordinated processing of medical data for research in the field of AI exclusively in Moscow within the framework of the experimental legal regime[325] or to individual startup projects[326], which creates obstacles on the path of scientific and technological progress.

The development of medical AI systems thus falls under a number of exemptions for non-cooperative data processing, as research in this area pursues a scientific goal (advancing technology) and provides a public interest (improving the health care system through better health care services). Thus, algorithm developers and operators may lawfully, without any consent or notification to patients, process their medical data that was lawfully obtained as a result of medical care. We mentioned earlier that such a provision is acceptable as long as the right to privacy is guaranteed.

In any data processing and especially in cases where such processing is carried out without the consent of the data subject, the focus should be on organizational and technical measures for the protection of personal data. First of all, the protection of the information systems and databases themselves is of great importance: compliance with all the conditions of personal data processing (with or without the subject's consent) will be useless if the algorithm is vulnerable to external interference.

The international legal regulation in the field of personal data also touches upon this issue. Thus, the requirement to ensure data protection is stipulated in Art. 7 of the Convention ETS № 108, which is implemented through the prevention of accidental or unauthorized destruction or accidental loss of data, as well as the prevention of unauthorized access to data, their modification or dissemination. The GDPR in this respect enshrines a more thorough set of measures, which are organized into two data protection concepts according to Art. 45 of the GDPR:

— the concept of privacy by design, the essence of which is the preliminary prediction of privacy risks and vulnerabilities of the data processing system, as well as the adoption of technical and organizational protection measures;

— the concept of privacy by default, which is expressed through the adoption of technical and organizational measures ensuring, by default, the processing of only those data necessary for the specific purpose of processing.

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[325] On conducting an experiment to establish special regulation in order to create the necessary conditions for the development and implementation of artificial intelligence technologies in the subject of the Russian Federation – the city of federal significance Moscow and amending Articles 6 and 10 of the Federal Law «On Personal Data» : Federal Law of 24.04.2020 № 123-FZ // CL RF. 2020. № 17. Art. 2701.

[326] See: On experimental legal regimes in the sphere of digital innovations in the Russian Federation : Federal Law of 31.07.2020 № 258-FZ, ed. of 02.07.2021 // CL RF. 2020. № 31 (part I). Art. 5017.

The GDPR indicates the need to have systems in place to restore access to data, as well as ongoing monitoring of the effectiveness of the measures taken (Art. 40). Great attention is justifiably paid to the mechanism of preliminary assessment of the impact of processing on data protection (Art. 35 GDPR) and the existence of a procedure for consultation of the operator with the supervisory authority in case the measures taken prove insufficient (Art. 36 GDPR, Protocol CETS № 223). One of the key elements of the privacy mechanism is depersonalization of data. Deletion of personal data after achieving the purposes of their processing is an ultimatum way to protect the rights of the subject, as it implies the disappearance of the very object of legal protection. Despite its effectiveness, this method is absolutely incompatible with STP. An alternative to data deletion is data anonymization (anonymization or pseudonymization), the essence of which is to split the data into fragments, each of which separately cannot identify the subject.

However, researchers have noted that the use of AI systems significantly reduces the effectiveness of de-personalization because algorithms are able to identify the patient's identity from the smallest individual features of clinical data[327]. For this reason, a more viable alternative is blockchain technology[328], which will allow data to be broken down into multiple, meaningless blocks, each of which cannot be removed or altered individually. In addition, there is an inverse relationship between the degree of anonymization and the value of the data for analysis[329]: detailed personal data are more valuable (both theoretically and materially)[330], making the use of cryptographic data encryption methods the most relevant.

In our opinion, a universal international legal instrument enshrining the obligations in the field of personal data protection is yet to be elaborated. This work will be quite difficult, given the technological gap that currently exists between technologically developed and developing countries. Particular care should be taken when using the currently available developments, including those of institutions such as the EU and the Council of Europe. The orientation towards extreme individualism and formalism within these institutions cannot be supported in the development of universal regulators. At the same time, the set of requirements proposed by them both for the protection of personal data (including health information) and for ensuring the security of their processing, including with the use of AI (i.e. automated processing) is of certain interest. Nevertheless, the regional and ideological specificity of the legal

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[327] Tschider C.A. Op. cit. P. 443; Opinion № 4/2007 on the Concept of Personal Data: adopted by the Article 29 Data Protection Working Party (EU advisory body), WP136 on 20.06.2007 [Electronic resource] // European Union: [website]. URL: https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2007/wp136_en.pdf (date of access: 30.05.2023).

[328] Ivshin A.A. Op. cit. P. 141; Maxmen A. AI researchers embrace Bitcoin technology to share medical data / A. Maxmen // Nature. 2018. Vol. 555. № 7696. P. 293-294.

[329] Savelyev A.I. Problems of Application of Legislation... P. 61; Ohm P. Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization / P. Ohm // UCLA Law Review. 2010. № 57. P. 1704.

[330] Dmitrik N.A. On the legal nature of consent to the processing of personal data / N.A. Dmitrik // Zakonodatelstvo. 2018. № 5. P. 47.

framework of these actors should be taken into account, as it requires significant adjustments, including taking into account the experience of the Russian Federation, as indicated by the imbalance between the «competing» rights and values, such as: privacy, protection of life and health, freedom of circulation of information for scientific purposes, etc.

Thus, the legal regulation within the European institutions is based on an unjustified priority of life and health protection over the confidentiality of personal data, as well as contains restrictions on the subject's right to exercise control over his/her personal data. In this regard, it is necessary to clarify the condition of personal data processing without the subject's consent by including an additional condition on the objective impossibility of obtaining the subject's consent or the exclusion of such exceptions to the collection of personal data.

At the same time, the effectiveness of the existing regulation currently depends to a greater extent on the practice of its application and on the dissemination of better software measures to detect and suppress threats to the processing of personal data. The envisaged legislative and organizational-technical measures are sufficient and can ensure the protection of personal data to the extent that the security of such data does not depend on technological competition, methods of unauthorized access and protection of information systems.

§ 3.3. Quality control of intelligent medical systems

Proper quality assessment of medical intelligent systems is of fundamental importance because lives and health of people depend on the performance of medical algorithms. Establishment of a balanced, efficient and transparent procedure for quality control of AI systems before their admission into civil turnover will facilitate the realization of the mechanism of bringing to responsibility for the harm caused by algorithms due to a clear distribution of responsibilities between the participants of relations complicated by AI. The international unification of the procedure and criteria for evaluating intelligent systems will make it possible to create a single quality standard for AI developments, which will increase the safety of their operation and facilitate cross-border exchange and trade in medical technologies and services.

First of all, we need to define the criteria for assessing the quality of AI. Since at the moment the liability for harm caused by AI is shared between the healthcare provider and the patient (§ 3.4 of the dissertation), it is critical to establish clear and formally defined criteria for the performance of the algorithm, so that the interested party can make an informed decision about the possibility of using intelligent technologies in the intervention process.

Thus, the performance of AI can be evaluated by the following criteria, which are called «error matrix»[331]:

— true positive (hereinafter – TP), when the algorithm indicates the existence of a certain fact, and this fact exists in reality;

— false positive (hereinafter – FP), when the algorithm indicates the existence of a certain fact, but this fact does not exist in reality;

— true negative (hereinafter – TN), when the algorithm indicates the absence of a certain fact, and this fact does not exist in reality;

— false negative (hereinafter – FN), when the algorithm indicates the absence of a certain fact, but this fact exists in reality.

A fact may be a statement of the presence or absence of a particular phenomenon (e.g., pathology on a radiograph) or a classification of a phenomenon (e.g., determining the type of pathology). We can extrapolate this error matrix to any function that the algorithm performs. The evaluation system is based on correlation of the output data of the intellectual program with the «authentic» reality, which is determined through a set of expert opinions: the decision reached by a qualified specialist or a medical commission (in ambiguous cases) will be considered correct.

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[331] How to assess the quality of medical neural networks? [Electronic resource] // CELSUS.AI: site of the AI-technology platform «Celsus». 2020. 13 October. URL: https://celsus.ai/blog/kachestvo-nejrosetej/ (date of access: 30.05.2023); Labintsev E. Metrics in machine learning tasks [Electronic resource] // HABR.COM: information resource for IT-specialists «Habr». 2017. 12 May. URL: https://habr.com/ru/company/ods/blog/328372/ (date of access: 30.05.2023).

The existing criteria of AI quality assessment, which are called metrics, are based on various combinations of error matrix elements. The most common metrics are the following[332]:

— Sensitivity / Recall, which refers to the ability of an algorithm to reliably determine the existence of a fact. Formula: TP / (TP+FN) * 100%;

— Specificity, which refers to the ability of an algorithm to reliably determine the absence of a fact. Formula: TN / (TN+FP) * 100%;

— Accuracy, which refers to the algorithm's ability to come to correct conclusions regarding the entire volume of cases studied. Formula: (TP+TN) / all surveys * 100%;

— Precision, which refers to the algorithm's ability to identify true positive facts in the total volume of positive facts identified. Formula: TP / (TP+FP).

It is important to realize that each of these metrics has its own functional purpose and should be used in conjunction with other metrics to avoid distorting the quality assessment. Thus, the Accuracy metric is not able to reflect the efficiency of the algorithm when analyzing heterogeneous data because the metric does not reflect the «selectivity» of the algorithm[333]. For example, in a group of 100 people, 80 of whom are sick and 20 of whom are healthy, an accuracy-Accuracy AI of an «impressive» 80% could mean that the algorithm simply determined the presence of disease in the entire study group without distinguishing between positive and negative cases, indicating a significant defect in the algorithm.

Specificity, in practice, reflects the number of referrals for additional testing when disease is falsely detected[334]. Sensitivity, in turn, involves the system's ability to identify facts and qualify classes in the overall mass of data, while Precision identifies the risk of mischaracterizing a fact[335]. Awareness of the value of each metric will thus not only allow us to assess the quality of the system, but will also facilitate the integrated application of multiple algorithms to cross-check each other's results.

Since each of these criteria reflects a simplified (one-aspect) assessment of AI performance, researchers are searching for the most accurate comprehensive metric that reflects the actual efficiency of the algorithm. One of the most popular combined metrics is ROC AUC (ROC – Receiver Operating Characteristic, AUC – Area Under Curve), which is measured by the area covered by the curve. In this regard, this metric allows not only to objectively evaluate the performance of the algorithm, but also to provide the interested party with information about the effectiveness of the AI in a visual form. The details of the application of this metric are outlined in Appendix D.

In our opinion, regardless of the performance of each specific metric, multiple metrics should be combined within a medical AI quality control system: using the evaluation criteria together will provide

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[332] Ward Powers D.M. Flinders University Evaluation: From precision, recall and F-measure to ROC, informedness, markedness & correlation / D.M. Ward Powers // Journal of Machine Learning Technologies. 2011. Vol. 2. № 1. P. 37-63.

[333] How to assess the quality of medical neural networks? URL: https://celsus.ai/blog/kachestvo-nejrosetej/.

[334] Labintsev E. Op. cit.

[335] How to assess the quality of medical neural networks? URL: https://celsus.ai/blog/kachestvo-nejrosetej/.

the most comprehensive view of the algorithm's performance. We see the question of the excessiveness of quality assurance methodologies as irrelevant, given the scope of application of AI systems and the importance of the values protected.

Metrics in general can be used to authorize the admission of AI developments into civil circulation. In this context, there is a problem of quantifying the thresholds of metrics for regulatory enshrinement. For example, some researchers have suggested that a minimum ROC AUC value of 0.8 (80%) should be set for an intelligent system to be allowed for use in medical practice[336]. We believe that this issue deserves a separate, and not legal, study.

At the same time, the analysis of medical experts' works allows us to derive a general rule when determining the threshold values of metrics: if the AI performance indicators are equal or higher than those of a human expert with respect to a particular field of medicine, such an algorithm can be used in practice[337]. Accordingly, the thresholds for each metric (1) should not be absolute and unworkable in practice, (2) will vary depending on the medical application. The above rule is sufficiently formalized and justified to be formalized in law. In our opinion, it is necessary to objectively assess the possibilities of AI and not to idealize modern technologies, making exaggerated demands to them to the detriment of the practical benefits that the relevant development can bring. This position, in particular, is reflected in the Code of Ethics for Developers, which is an annex to EU Resolution № 2015/2103.

Earlier we pointed out that medical AI systems have the status of medical devices, which makes it necessary to apply to the relations related to their production, introduction into civil circulation and operation a set of administrative and supervisory procedures that regulate the procedure for the circulation of medical devices. The essence of this legal regime is the imposition of special safety and quality requirements on manufacturers and medical AI products themselves, compliance with which is established in the process of undergoing a set of procedures. Based on the results of such control, the medical device is registered and allowed for use in medical practice.

Each state independently determines the procedure for circulation of medical devices on its territory, therefore, to date, this mechanism is predominantly territorial in nature. However, in rare cases by forces of regional economic associations unification of regulation in this area is carried out, an example of which is the EU Regulation № 2017/745 of 05.04.2017 «On medical devices»[338] or the Agreement on common principles and rules of circulation of medical devices within the EEU of 23.12.2014[339]. Moreover, as Prof. T.N. Neshataeva notes, the market of common certification of goods, including the

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[336] How to assess the quality of medical neural networks? URL: https://celsus.ai/blog/kachestvo-nejrosetej/.

[337] Use of artificial intelligence in clinical practice / D.N. Borisov [et al] // Clinical Pathophysiology. 2019. Vol. 25. № 2. P. 28.

[338] Regulation (EU) № 2017/745 of 05.04.2017 on medical devices, amending Directive № 2001/83/EC, Regulation (EC) № 178/2002 and Regulation (EC) № 1223/2009 and repealing Council Directives № 90/385/EEC and 93/42/EEC // Offic. J. of the Europ. Union. Ser. L. 5.5.2017. L117. P. 176–332.

[339] Agreement on Uniform Principles and Rules for the Circulation of Medical Devices (Medical Devices and Medical Equipment) within the EEU of 23.12.2014, as amended on 30.12.2021. // CL RF. 2016. № 20. Art. 2775.

sphere of medical devices, services and medicines on the basis of common standards and practices of the EEU Court has already started to emerge within the EEU[340].

We see further international cooperation to harmonize administrative procedures and technical regulations in the area of control over the circulation of medical devices as an extremely positive trend. Creation of international systems for registration of medical devices and quality certification will significantly simplify the commercial use of AI developments, as well as unite the standard-setting and law-enforcement potential of national legislators. However, first of all, we must determine the state of the current regime of control over the circulation of medical devices and identify promising areas for its improvement in connection with the use of AI.

Analysis of applicable international regulation (sources are indicated above) and Russian legislation, in particular Article 38 of Law № 323-FZ, allows us to identify the following elements of the medical devices circulation regime: (1) typologization of products into several classes depending on risk and danger; (2) passing technical and clinical tests, as well as other examinations of quality and safety of medical devices; (3) state registration of medical devices; (4) special requirements for the production, introduction into civil circulation, storage, transportation, adjustment, operation, maintenance and disposal of medical devices; (5) requirements for the content of technical and operational documentation.

At the same time, we do not find any specificity in the treatment regime for medical AI systems specifically. One of the main features of AI that can significantly complicate quality and safety control has been overlooked, namely its learnability, whereby an algorithm can change its performance during its lifecycle[341] and thus become unsafe without proper controls, even after it has been registered as a medical device. This fact necessitates the introduction of post-registration control and maintenance procedures for the medical device, and, moreover, during the entire life cycle of the system.

Changing AI behavior is possible (1) when the developer updates the program, (2) when the system is reconfigured by its operator, or (3) when the algorithm functions on the basis of continuous learning. In the first two cases, the unpredictability of AI system behavior is insignificant, since these processes are under human control. In turn, it is extremely difficult to control the continuous learning and development of an algorithm after its registration, because such control is impossible without a well-established mechanism of feedback from developers and constant monitoring of the system's performance.

Due to the absence of special international legal regulation of quality control of medical AI, self-regulatory tools are of great practical importance. In this context, a special role is played by the IMDRF,

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[340] Neshataeva T.N. Eurasian integration: the modern stage / T.N. Neshataeva // Pacta sunt servanda in the era of change: to the 85th anniversary of O.I. Tiunov: a collection of articles / T.Y. Khabrieva, T.O. Korolkova, A.Y. Kapustin, et al; ed. by A.Y. Kapustin. Moscow: Institute of Legislation and Comparative Law under the Government of the Russian Federation; Publishing House «Jurisprudence», 2022. P. 71.

[341] Kiseleva A.Y. Op. cit. P. 32.

whose guidelines are the most relevant, elaborated and universal, which determines the need for their legalization. The relevant indication is contained, in particular, in subpar. «c» para. 1 of Art. 3 of the 2014 EEU Agreement on Uniform Principles and Rules for the Circulation of Medical Devices, which also supports our proposal.

The experience of the Russian legislator in connection with the introduction in spring 2022 of a group of national standards developed within the framework of the National AI Development Strategy for the period until 2030 and devoted exclusively to the specifics of medical intelligent systems is also noteworthy. Thus, national standards of GOST R 59921.* series, which regulate various aspects of the procedure for circulation of AI systems for medical use, came into effect on 01.03.2022 (for example, GOST R 59921.2-2021[342] stipulates the program and methodology of technical tests of such algorithms). It is noteworthy that these standards are not a copy or an official translation of already existing international standards, therefore, they enshrine a number of relevant novelties concerning special procedures and rules in the field under consideration. In many respects, these documents embodied many of the well-founded suggestions that had been offered by specialists in the scientific literature.

In particular, we can find a solution to the problem of controlling systems with continuous learning in the National Standard GOST R 59921.3-2021[343]. The document stipulates the manufacturer's obligation to describe in the technical and operational documentation all risks and changes in the operation of the AI system that may be caused by continuous learning (clause 4.2.1), as well as to prepare a change management plan containing the most complete description of possible algorithm changes during adaptations, including their rationale, any possible changes in the input data and updated program performance characteristics. Despite the innovation of GOST R 59921.3-2021 in terms of AI regulation, the above standard, in our opinion, is insufficiently complete, only conceptually noting the directions of solving problems related to lifelong learning.

In our opinion, the standards system should also enshrine a procedure for regular checks of AI systems efficiency on manufacturer's test datasets, which will make it possible to trace possible deviations in algorithm performance. The frequency of such checks should relate to the intervals between algorithm changes and the start of its clinical validation[344] – this parameter should be displayed in the

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[342] GOST P 59921.2-2021. Artificial intelligence systems in clinical medicine. Part 2. Program and methodology of technical tests [Electronic resource] ; introduced 2022-03-01 // Federal Agency for technical regulation and metrology: [website]. Moscow, 2021. URL: https://protect.gost.ru/v.aspx?control=8&baseC=6&page=0&month=5&year=2022&search=59921.2–2021&RegNum=1&DocOnPageCount=15&id=232102 (date of access: 30.05.2023).

[343] GOST P 59921.3-2021. Artificial intelligence systems in clinical medicine. Part 3. Change management in artificial intelligence systems with continuous learning [Electronic resource] ; introduced 2022-03-01 // Federal Agency for technical regulation and metrology: [website]. Moscow, 2021. URL: https://protect.gost.ru/v.aspx?control=8&baseC=6&page=0&month=5&year=2022&search=59921.3–2021&RegNum=1&DocOnPageCount=15&id=232146 (date of access: 30.05.2023).

[344] Clinical validation means confirmation of the ability of the artificial intelligence system to produce clinically relevant output data related to the intended use of the artificial intelligence system within the framework of the functional purpose established by the manufacturer (clause 3.10 of GOST R 59921.1-2022).

already mentioned change management plan. In turn, the test sets themselves should, if possible, be formed by several independent compilers to ensure the reproducibility and generalizability of the model, in other words, to ensure the objectivity of the assessment.

The scientific literature also proposes to normatively fix the mechanism of interaction between AI developers and users, which will provide (1) prompt feedback in case of errors in the program operation, (2) consultation about the rules of the system operation and (3) explanation of the result obtained by it[345]. We cannot but agree on the need for legal regulation of this measure, which will contribute to increasing transparency and accountability of AI behavior. It is noteworthy that the mentioned GOST R 59921.3-2021 also regulates the interaction between manufacturers and users of algorithms through the system of notifications and continuous monitoring of the product operation safety. However, this interaction format is limited by the scope of the standard, which applies only to continuous learning AI systems.

Other national standards from the previously designated series of GOST R 59921.* enshrine many other rules and requirements that can be unified and enshrined in the sources of international law. The following procedures are of interest:

– **Technical trials**, are regulated in GOST R 59921.2-2021. In addition to fixing the criteria for attributing software to medical devices (discussed in § 2.1 of the dissertation), this standard establishes a number of requirements for the program and methodology of technical tests, which are understood as tests to determine whether the algorithm properties correspond to its stated characteristics (clause 2.15), which must be shown in the technical documentation (clause 2.16). Along with technical documentation, there is also operational documentation (clause 2.17), intended for the consumer, in which the conditions and rules of operation, the values of the main parameters and properties of the system guaranteed by the manufacturer, as well as warranty obligations and information on its decommissioning must be regulated.

– **Clinical trials**, regulated in GOST R 59921.1-2022 [346]. The standard enshrines several stages of clinical trials (hereinafter – CT), each of which is regulated separately: the AI system must undergo clinical evaluation, including analytical and clinical validation, as well as the establishment of clinical linkage (clause 4.1). The CT results confirm (1) the algorithm's ability to accurately, reproducibly, and reliably generate the intended computational results from input data, (2) its compliance with the manufacturer's stated requirements and the user's needs, and (3) the AI's ability to generate output data that is consistent with the clinical factors of the study site and the intended purpose of the algorithm.

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[345] Kiseleva A.Y. Op. cit. P. 33.

[346] GOST P 59921.1-2022. Artificial intelligence systems in clinical medicine. Part 1. Clinical evaluation; introduced 2022-06-28 [Electronic resource] // Federal Agency for technical regulation and metrology: [website]. Moscow, 2022. URL: https://protect.gost.ru/v.aspx?control=8&baseC=6&page=0&month=6&year=2023&search=ГОСТ%20Р%2059921.1-2022&RegNum=1&DocOnPageCount=15&id=233962 (date of access: 30.05.2023).

Much attention is paid to the CT program (clause 5.4.2), at the stage of preparation of which ethical issues of application of the algorithm and its CT may be considered (clause 5.2). The methodology of AI systems testing implies the use of a data set as a research subject, which is obtained with the participation of a human, and the algorithm results themselves are evaluated according to the error matrix we have already mentioned. It is noteworthy that the national standard in clause 6.2 sets forth the most detailed and complete list of existing metrics that can be used in algorithm testing.

– Evaluation and control of operational parameters, regulated in GOST R 59921.4-2021[347]. This national standard fixes a branched system of AI operational parameters (accuracy, type of input data, purpose, principle of training organization, etc.) and methods of their evaluation. Many control procedures are at the discretion of the manufacturer, who should reflect them in the technical documentation, including the frequency of quality assessment. Clause 5.2 of the standard recommends that the operational parameters of the system should be verified throughout its life cycle.

The standard provides for measuring the effectiveness of the algorithm by three metrics – sensitivity, specificity and accuracy. As we mentioned earlier, these evaluation criteria are not sufficient: the list should be supplemented with complex metrics, for example, AUC ROC. In addition, a rule on continuous monitoring of algorithm performance should be enshrined as a requirement, but not a recommendation, specifying maximum intervals between checks. The introduction of security monitoring of intelligent systems at the pre- and post-registration stages during the life cycle will also avoid the need to re-register such systems[348].

– General requirements for exploitation, regulated in GOST R 59921.6-2021[349]. The presented standard establishes requirements to the form and content of technical and operational documentation, including through the fixing of requirements to the equipment (e.g., Internet connection speed) and the user (the need for training to work with AI, the obligation to study the user manual, etc.).

The considered standard, the only one of the GOST R 59921.* series, regulates the procedure of (1) internal control of AI systems, in which the manufacturer checks purely technical indicators of the systems, for example, response time, correctness and completeness of the processing results, etc., with a periodicity determined by him; (2) external control of AI-systems, in which the work of algorithms is

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[347] GOST P 59921.4-2021. Artificial intelligence systems in clinical medicine. Part 4. Evaluation and control of operational parameters; introduced 2022-03-01 [Electronic resource] // Federal Agency for technical regulation and metrology: [website]. Moscow, 2021. URL: https://protect.gost.ru/v.aspx?control=8&baseC=6&page=0&month=5&year=2022&search=59921.4–2021&RegNum=1&DocOnPageCount=15&id=232255 (date of access: 30.05.2023).

[348] Kiseleva A.Y. Op. cit. P. 33.

[349] GOST P 59921.6-2021. Artificial intelligence systems in clinical medicine. Part 6. General requirements for operation [Electronic resource] ; introduced 2022-03-01 // Federal Agency for technical regulation and metrology: [website]. Moscow, 2021. URL: https://protect.gost.ru/v.aspx?control=8&baseC=6&page=0&month=5&year=2022&search=59921.6–2021&RegNum=1&DocOnPageCount=15&id=232204 (date of access: 30.05.2023).

checked on the basis of metrics. External control is required both when changes are made to the AI and during its life cycle as an integral element of post-registration monitoring.

The existing system of national standards of the Russian Federation demonstrates the progress of the legislator and law enforcer in establishing the basis for the regulation of AI technologies in medicine. In our opinion, almost all measures to ensure the quality and safety of AI, which are reflected in the above national standards of GOST R 59921.* series, are reasonable and should be taken into account in the development of international legal regulation in the field of circulation of smart medical devices.

Although control over the circulation of medical devices is the main factor ensuring the admission of high-quality intellectual developments into medical practice, we cannot ignore the general requirements for the participants of relations in the field of creation and use of algorithms regardless of the sphere of application. The analysis of scientific literature and international legal acts shows that the greatest number of responsibilities are imposed on manufacturers of AI systems (especially – developers), which has quite obvious grounds. According to the 2017 Asilomar Principles for AI, it is the algorithm developers who play a key role in shaping the moral consequences, including misuse, of AI.

First of all, developers should take a set of measures aimed at excluding or minimizing possible risks of harm caused by the AI system[350]. In doing so, as some authors have noted, designers must take the position that some individuals may use a smart device intentionally to cause harm[351]. The implementation of these measures, in our opinion, should be based on principles similar to the concept of privacy by design from GDPR[352]. For the legal regime of AI-technologies, this concept should be transformed into the principle of protection by design, the essence of which would be to build into the algorithm of program measures and constraints aimed at preventing harm. Requirements to protect systems from unauthorized access by third parties should also be considered an integral part of the concept.

Much attention is paid to the requirements for participants in AI relationships in the Robotics Charter, which is an Annex to EU Resolution № 2015/2103 (hereinafter referred to as the Robotics Charter). This act stipulates the obligation of designers to ensure: (1) the possibility of human involvement in the decision-making process of the system at any time, (2) the presence of a function for canceling the action, (3) the presence of an emergency switch. These rules are definite and reasonable, correspond to the principles of AI regulation specified in § 2.2 of the dissertation, and, therefore, can be enshrined in sources of law.

The Robotics Charter also provides some responsibilities for the users (operators) of the algorithms. In particular, it is prohibited to (1) use AI systems for purposes contrary to ethical and legal standards and norms, (2) make modifications that could result in the device being used as a weapon.

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[350] Baranov P.P. Op. cit. P. 42.
[351] Arkhipov V.V. On Some Issues of Theoretical Foundations... P. 168.
[352] Ibid. P. 169.

Since existing medical algorithms are mainly used to assist in decision making, it seems reasonable to assign the user the responsibility of controlling the AI during its operation (for example, a surgeon should not only set a clinical task to the algorithm, but also control the course of the operation).

In order to ensure safety, it is of great importance to assess the risks of operating intelligent systems. In this regard, the Code of Ethics for Developers (part of the Robotics Charter) enshrines the obligation to predict the expected level of safety of AI developments, as well as to take the necessary measures in advance to minimize the risk of negative consequences. If the development involves an insurmountable risk of harm, it should be assessed and risk management protocols prepared. The risk assessment mechanism is also regulated in the 2019 OECD Council Recommendation on AI, whose clause 1.4(c) enshrines the need for continuous risk monitoring of AI systems during their lifecycle. The need for risk assessment is also reflected in the UNESCO Recommendation on the Ethical Aspects of AI of 2021, which indicates the need for the state to have an obligation to identify and analyze the benefits, challenges and risks associated with the application of AI technologies (para. 50). These requirements can be summarized into a special legal principle of risk management (discussed in detail in § 2.2 of the dissertation), which should naturally apply to the use of AI in medicine.

In our opinion, it is also necessary to consider separately the requirements for AI training, the quality of which determines the efficiency and safety of the algorithm. The quality of the predictive model embedded in the AI system will not matter if the program is not properly trained on a large amount of data. At the same time, it is learnability as a property of AI that carries most of the risks associated with the use of algorithms and the possibility of their uncontrolled development. Despite the importance of this stage of AI development, we do not find in the current sources of international law any norms dedicated to the training of AI systems.

We find an indication of the need to regulate the training of algorithms only in the WMA's 2019 Statement on Augmented Intelligence in Health Care, whose drafters noted that data structure, data integrity are the main issues that need to be addressed in the development of AI systems in health care. According to the reasonable observation of experts, training datasets are created by humans and therefore may reflect bias and contain errors. Therefore, when evaluating the effectiveness of a predictive model, training and test datasets should be interrelated. Unfortunately, we do not find more detailed regulation of the AI training stage in the acts of international non-governmental organizations either.

Training of the system is carried out on the basis of processing of training, validation and test datasets[353], the content and order of use of which during the creation of AI significantly affects the

[353] Training datasets for neural networks: how to train and test a neural network in Python [Electronic resource] // RADIOPROG.RU: portal of technical information in the field of radio electronics, programming, IT and telecommunications. 2020. 7 February. URL: https://radioprog.ru/post/792 (date of access: 30.05.2023); Kurakin A. Validation set [Electronic resource] // ALEXANDERKURAKIN.BLOGSPOT.COM: techblog Alexander Kurakin. 2018. 20 August. URL: https://alexanderkurakin.blogspot.com/2018/08/validacioniy-nabor.html (date of access: 30.05.2023).

efficiency of the algorithm. It is crucial that the data from each dataset should not be mixed or duplicated, and should be mutually representative. Otherwise, adequate and reliable performance evaluation will be impossible – the algorithm will memorize the data already processed as a result of training, thus reducing its predictive capabilities. This effect has been termed «overfitting»[354]. Thus, to ensure an objective quality assessment, the model should be closed (i.e., restrict the learning function) before it is validated. The experts also suggest that, if possible, several independent parallel tests should be performed to check the reproducibility of the algorithm[355].

The analysis of specialized literature allows us to derive many other recommendations and rules, compliance with which will ensure quality training of the algorithm. We believe that this issue requires a separate and detailed study. At the same time, this direction of ensuring AI security is practically not regulated by the norms of international and integration law, which is a significant gap in the legal regulation of AI technologies.

[354] Kapatsa E. Train Data [Electronic resource] // HELENKAPATSA.RU: Elena Kapatsa's project devoted to machine learning. 2021. 4 March. URL: https://www.helenkapatsa.ru/trienirovochnyie-dannyie/ (date of access: 30.05.2023).

[355] Collins G.S. Reporting of artificial intelligence prediction models / G.S. Collins, K.G.M. Moons // The Lancet. 2019. № 393 (10181). P. 1577-1579; Antoniades Ch. Op. cit. P. 123.

§ 3.4. Liability for harm caused by artificial intelligence for medical use

The problem of bringing to responsibility for the harm caused by AI is one of the most complex and discussed in the scientific literature. Specialists repeatedly emphasize the need for legal regulation of the mechanism of bringing to responsibility for the actions of algorithms[356]. This problem is also recognized by the Russian law enforcer: the development of liability mechanisms (including guilt-free) and methods of compensation for damage caused by AI with a high degree of autonomy is mentioned in paragraph 2 of Section II of the Concept for the development of regulation of relations in the field of AI technologies and robotics up to 2024[357].

Causing harm by medical algorithms, of course, has specificity: medical intervention is a priori associated with the risk of causing harm to human life and health. In this paragraph it is tort liability that will be investigated, since the infliction of harm to life and health in the performance of a contract, as a rule, is also carried out according to the rules of compensation for harm in the framework of a tort obligation (example – Art. 1084 of the Civil Code). In turn, the issues of administrative and criminal liability fall within the sphere of discretion of states, except for international crimes and crimes of international nature, the compositions of which do not cover cases of malicious use of AI. At the same time, the specificity of guilt and causality can be traced in the framework of the tort as well.

Numerous cases of AI systems causing harm are already occurring today. In the spring of 2018, an unmanned Uber car performed a hit-and-run collision with a pedestrian. The AI recognized the person, but decided not to stop driving, as the developers intentionally overestimated the threshold of collision recognition to minimize the cases of false alarms of the algorithm, while the test driver did not follow the situation on the road[358]. We can also see cases of algorithms causing harm in the field of medicine. In 2018, the Watson for Oncology program began prescribing incorrect medications to patients with cancer, which could threaten their health. One of the possible causes is called poor training of the AI system, the training dataset of which was not representative[359].

The presented cases are characterized by the absence of any intent to cause harm, which shifts the focus from «hostility of machines» to quite ordinary causes of what happened: negligence and bad

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[356] Balkin J.M. The Path of Robotics Law / J.M. Balkin // California Law Review Circuit. 2015. № 6 (72). P. 45-60.

[357] On approval of the Concept of development of regulation of relations in the field of artificial intelligence technologies and robotics until 2024 : Order of the Government of the Russian Federation from 19.08.2020 № 2129-r // CL RF. 2020. № 35. Art. 5593.

[358] Efrati A. Uber Finds Deadly Accident Likely Caused By Software Set to Ignore Objects On Road [Electronic resource] // THEINFORMATION.COM: online newsletter «The Information». 2018. 7 May. URL: https://www.theinformation.com/articles/uber-finds-deadly-accident-likely-caused-by-software-set-to-ignore-objects-on-road (date of access: 30.05.2023).

[359] Spitzer J. IBM's Watson recommended 'unsafe and incorrect' cancer treatments, STAT report finds [Electronic resource] // BECKERSHOSPITALREVIEW.COM: online newsletter «Becker's Healthcare». 2018. 25 July. URL: https://www.beckershospitalreview.com/artificial-intelligence/ibm-s-watson-recommended-unsafe-and-incorrect-cancer-treatments-stat-report-finds.html#:~:text=IBM's%20Watson%20supercomputer%2C%20once%20hailed,internal%20IBM%20documents%20reviewed%20by (date of access: 30.05.2023).

faith of the relevant participants in AI relationships[360]. We do not deny the risk of intentionally creating algorithms with deviant attitudes, as exemplified by the AI developed by MIT Media Lab specialists to simulate mental disorders and the desire to cause harm[361]. At the same time, prosecution in such cases, as well as in the case of intentional hacking of an intellectual program, will not create any problems, since the composition of the tort and the causer of harm in this case are obvious.

Just by the example of a few of these incidents, we can see a number of complexities that arise exclusively in connection with the use of AI. The specifics lie in the key features of the technology: its autonomy and learnability[362], which make AI behavior unpredictable, posing an increased risk in the medical field.

The solution of the problem of liability for harm caused by AI directly depends on the scope of its legal capacity[363]. The models of liability for AI under human control and without it are radically different. Given the current level of technological development, it is only right to impose legal liability on a human being, to whom the algorithm is controlled. This is repeatedly mentioned in international normative acts and sources of integration law: EU Resolution № 2015/2103, the OECD Council Recommendation on AI of 2019, and the UNESCO Recommendation on the Ethical Aspects of AI of 2021.

At present, granting AI legal personality and holding algorithms legally accountable are matters of the distant (albeit imminent) future[364], as we also noted in § 2.1 of the dissertation. As experts note, today the use of AI systems in healthcare does not cancel the need for a relationship between patient and doctor, while such systems only supplement the medical care provided by the doctor and are used as MDSS[365]. Therefore, we will focus only on the conceptual possibility of bringing the algorithm itself to tort liability and then elaborate on the relevant concepts, the basic premise of which is the human controllability of AI systems.

First of all, let us consider the nature of civil liability, which is understood as a type of protective obligations arising from the law or contract, the essence of which is to recover from the offender in favor of the victim material sanctions imposing additional burdens on the offender and aimed at restoring the violated property sphere of the victim[366]. Liability performs a number of functions, among which traditionally distinguished compensatory, punitive, preventive, educational and regulatory. The very institute

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[360] Nikitenko S.V. Concepts of tort liability for damage caused by artificial intelligence systems / S.V. Nikitenko // Herald of Economic Justice of the Russian Federation. 2023. № 1. P. 158.

[361] Norman AI [Electronic resource]: World's first AI project dedicated to simulating mental illness / MIT Media Lab. Boston, 2018. URL: http://norman-ai.mit.edu/ (date of access: 30.05.2023).

[362] Malyshkin, A.V. Integrating artificial intelligence into public life: some ethical and legal problems / A.V. Malyshkin // Vestnik SPBU. Law. 2019. Vol. 10. № 3. P. 446.

[363] Laptev V.A. Op. cit. P. 89-98; Ponkin I.V. Op. cit. P. 96.

[364] Eidenmueller H. Op. cit.; Wein L. Op. cit. P. 105-106.

[365] See: WMA Statement on augmented intelligence in medical care. URL: https://www.wma.net/policies-post/wma-statement-on-augmented-intelligence-in-medical-care/ (date of access: 30.05.2023).

[366] Russian civil law : textbook : in 2 vol. / [V.V. Vityransky et al.] ; ed. by E.A. Sukhanov. 2nd ed., rev. and supp. M.: Statut, 2011. Vol. 1: General part. Property law. Inheritance law. Intellectual rights. Personal non-property rights. P. 445.

of responsibility is directed at the subject: the modern level of legal culture, as a rule, does not allow to find examples of bringing things to responsibility in the legal orders of developed states. Anthropocentric understanding of the institute of responsibility leads some researchers to the idea of inadmissibility of bringing to responsibility AI, which cannot be re-educated or condemned[367].

This position embodies a simplistic view of the problem. It should be taken into account that civil liability as a legal institute has an autonomous content and is applied (1) in the presence of signs of legal composition (2) to subjects with certain legal properties. Liability is applied not to a person for his re-education, but to the subject of law in order to realize the functions of responsibility. From this point of view, for example, the reconfiguration of AI hyperparameters ensures the achievement of the goals of responsibility in the same way as the re-education of a human being.

The possibility of prompt intervention and change of AI behavior provides the implementation of preventive and educational functions of responsibility. The fact that the correction of the behavior of an autonomous subject will be carried out not through re-education as an independent change of the subject's own behavioral attitudes, but through direct external intervention by means of readjustment, from the legal point of view for the purposes of the institute of responsibility does not matter. The conceptual possibility of conferring legal personality on an AI naturally entails its tort capacity. In this context, the realization of preventive and educational functions of responsibility should be considered as a correction of the subject's legal will. Taking into account that AI can possess legal will, there is a prerequisite for the application of liability measures directly to the intellectual systems themselves, which, however, is hardly relevant today[368].

At present, given the lack of legal personality of the AI, the achievement of the relevant objectives of the institute of liability can be ensured through: (1) bringing to liability a legal or physical entity that uses the AI system in its activities, for example, a medical organization (by analogy with bringing to liability an employer for damage caused by an employee under Art. 1068 of the Civil Code); (2) creation of specialized insurance funds, which we will mention later.

At the same time, the autonomy of AI in the absence of its tortability leads to the dual position of participants of civil turnover, whose legal will is superimposed on the «will» of algorithms, which makes it difficult to achieve the goals of liability. By affecting the behavior of a human subject, traditional liability measures do not affect the decision-making mechanism of the AI itself either directly or indirectly (not all subjects have knowledge sufficient to make changes to the algorithm). In this regard, to achieve the goals of responsibility, the most effective measures are those aimed at adjusting the logical decision-making scheme, reconfiguring hyperparameters, and retraining the AI system, including its retirement from service.

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[367] Laptev V.A. Op. cit. P. 95.
[368] Nikitenko S.V. Concepts of tort liability for harm caused by artificial intelligence systems. P. 160-160.

Let us consider the specifics of the legal corpus delicti committed with the use of AI. The classical composition of the general tort includes the following conditions: (1) unlawful nature of a person's behavior; (2) the presence of harm; (3) a causal link between the behavior and negative consequences; (4) the guilt of the person who caused the harm[369]. The participation of an intellectual system in a protective obligation significantly complicates the qualification of the above conditions, which leads some researchers to the idea that a new special tort should be developed[370].

The causal relationship between illegal behavior and harm is subject to the greatest transformation. Algorithm performance is influenced by many factors: AI architecture, the methods and type of training used, the number and quality of training datasets, the setting of hyperparameters, and the method of operation. The specificity of medical systems can be traced in the fact that the direct realization of a clinical decision made by the AI is mediated by a set of human-information interactions, usually in the form of a doctor's evaluation of such a decision[371].

The multitude of factors affecting the operation of the algorithm indicates the unreasonableness of assigning responsibility to any particular group of persons[372]. The main prerequisite for liability is the actual ability of a person to influence the decision-making process of the system and control its use. Accordingly, in the event that an AI carrier leaves the possession of its owner as a result of unlawful actions of other persons or unlawful interference in the operation of the algorithm, the relevant participant in the AI relationship should be exempted from liability.

The conditions for bringing to responsibility, first of all, should be: (1) non-compliance by a person with the rules of production, transportation, storage, sale, operation, maintenance and decommissioning of the algorithm; (2) bad faith of a person who by his/her actions contributed to the infliction of harm or worsening of the consequences of its infliction; (3) assumption by a person of the risk of infliction of harm by the AI system. In case of violation by the participant of the AI-relationship of the requirements imposed on it by the law, technical and operational documentation, the causal link in case of violation of harm will be presumed.

It should be taken into account that causing harm to AI that has not been improperly trained is possible in two situations: when the algorithm has and has not passed public quality control (registration of the algorithm as a medical device). In the first case, we are dealing with improper supervision in the area of medical devices or user risk; in the second case, the manufacturer is fully liable for allowing the distribution of an uncertified and/or unregistered system.

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[369] Russian civil law : textbook : in 2 vol. / [V.V. Vitryansky et al.] ; ed. by E.A. Sukhanov. 2nd ed., rev. and supp. M.: Statut, 2011. Vol. 2: Obligatory law. P. 1084.

[370] Iriskina E.N. Op. cit. P. 67; Shevchenko A.S. Shevchenko. Tort obligations in the Russian civil law : textbook / A.S. Shevchenko, G.N. Shevchenko. Moscow: Statute, 2013. P. 68.

[371] Magrani E. New perspectives on ethics and the laws of artificial intelligence / E. Magrani // Internet policy review. 2019. Vol. 8. № 3. P. 8.

[372] Nikitenko S.V. Civil-law liability for harm caused by artificial intelligence / S.V. Nikitenko // Eurasian Law Journal. 2021. № 4 (155). P. 23.

Guilt as a condition for bringing to responsibility also acquires its specificity. It should be noted that in civil law guilt is not a subjective, mental category, but is understood as the failure of a person to take measures to prevent or suppress adverse consequences of his behavior with the degree of care and diligence required of him by the nature of the obligation, conditions of turnover or taking into account the environment in which such a person acted[373]. Caution should be exercised with regard to the constructions of truncated torts, which exclude guilt as a condition for liability and impose liability on one group of persons (e.g. users[374]). The imposition of sanctions regardless of guilt, on the one hand, contributes to the protection of the weaker party and optimizes the civil turnover, speeding up the resolution of conflict situations, but on the other hand, represents a serious deterrent to further AI developments. In healthcare, as an area of high social importance, more stringent standards of responsibility must inevitably be imposed on professional participants, including the principle of personal responsibility of a doctor for the consequences of decisions made by automated means (to be discussed later).

Fault is expressed in non-compliance with the requirements stipulated by law or contract, as well as in bad faith behavior. Accordingly, special attention should be paid to the formalization of rules and requirements to be observed at each stage of the algorithm life cycle, as well as to the proper preparation of technical and operational documentation. Over time, standards and rules for the development, distribution and operation of AI will be developed[375], Over time, standards and rules for the development, distribution and exploitation of AI will be developed, which will help to allocate areas of responsibility between participants in AI relationships, define criteria for their good faith behavior, as well as help to establish the cause of harm and qualify the elements of a tort. At the same time, the relevant system of requirements is already established within the framework of control over the circulation of medical devices (see § 3.3 of the dissertation).

Let us consider the existing concepts of tort liability for harm caused by AI and assess their applicability to the field of medicine. The absence of a special composition of the tort for intelligent systems leads to numerous attempts to extend to the relevant relations the existing compositions of torts, which often do not take into account the specifics of AI. As noted in paragraph «AF» of the EU Resolution № 2015/2103, if an autonomous system has committed an act based on its own decision, the standard rules on objective or no-fault liability are not sufficient, because traditional liability institutions do not take into account cases of damage caused by robots capable of self-learning. This position is also supported by many authors[376], indicating the need to adapt tort liability to AI technologies.

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[373] Russian Civil Law: Textbook. Vol. 2. P. 1090.

[374] Builov M. AI: irresponsible, but profitable [Electronic resource] // KOMMERSANT.RU: Kommersant electronic print edition. 2023. July 20. URL: https://www.kommersant.ru/doc/6111440 (date of access: 20.07.2023).

[375] Mosechkin I.N. Op. cit. P. 468.

[376] Tolochko O.N. Op. cit. P. 35-39.

The most widespread is the concept of applying the provisions on the source of increased danger, according to which the owner of the AI will be responsible for its actions, regardless of guilt (example: Art. 1079 of the Civil Code)[377]. This approach is based on the formal coincidence of the properties of the AI and the source of increased danger, namely: the impossibility of full control over the system by a human (this feature is enshrined in sec. 18 of the Resolution of the Plenum of the Supreme Court of the Russian Federation of 26.01.2010 № 1[378]).

The advantage of this approach is its practical applicability and effectiveness as a way to compensate for the harm caused. When deciding on the issue of liability, only the fact that the AI belongs to a certain person should be assessed, which in principle eliminates the problem associated with the difficulty of establishing a causal link and facilitates the process of liability attribution.

However, this concept has disadvantages that are inherent in any position of imposing liability on one particular group of persons. It is possible that the owner will be held liable for the harm caused by the algorithm due to a defect in the architecture, improper training or another element of its design at the development stage, which is unacceptable because the system owner does not and should not have sufficient qualifications and knowledge of the technology and cannot assess the effectiveness of AI and influence its performance[379]. According to the justified observation of some authors, the prosecution of this group of persons (owners and users in general) should be made dependent on the degree of their control over the behavior of the AI, which should be assessed in each case[380]. Some researchers insist on the presumption of the owner's guilt[381], while other authors focus on individuals' compliance with operating rules and their role in training the algorithm[382].

Another concept is also based on the application of the classical preliminary tort and consists in bringing liability on the basis of the rules on compensation for damage caused by defects in goods. According to this approach, the manufacturers of AI systems – developers, producers and sellers – should be held liable irrespective of fault. The mere fact that harm has been caused is considered proof of a defect in the system. Proponents of this concept note that such a liability mechanism would facilitate more careful tuning of algorithms during the testing phase and cumulatively improve the quality of the final product[383].

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[377] Vasiliev A.A. Artificial intelligence: legal aspects. P. 24.

[378] On the application by the courts of civil legislation governing relations on obligations as a result of causing harm to the life or health of a citizen: Resolution of the Plenum of the Supreme Court of the Russian Federation from 26.01.2010 № 1 // Bulletin of the Supreme Court of the Russian Federation. 2010. № 3.

[379] Laptev V.A. Op. cit. P. 92; Nikitenko S.V. Civil-legal responsibility for the harm caused by artificial intelligence. P. 23.

[380] Ibid. P. 95.

[381] Chelysheva N.Y. Op. cit. P. 22.

[382] Mosechkin I.N. Op. cit. P. 470.

[383] Ibid. P. 468.

The criticism of this approach is obvious: the guiltless imposition of responsibility on developers can significantly slow down AI research. To minimize risks, intelligent systems will become less and less autonomous, and the number of programmable action patterns will increase, which will negatively affect the efficiency of algorithms. It should also be taken into account that manufacturers and sellers of smart devices, as well as software distributors have limited or no ability to make changes to the algorithm, therefore, such persons should be exempted from liability in case of implementation of an algorithm that has passed quality control[384] (registered as a medical device).

However, this concept is reflected in EU Resolution № 2015/2103. According to paragraphs AD-AI of the «Introduction» section, the concept is currently in force in the territory of the EU countries, according to which the liability is brought on the basis of the provisions on the manufacturer's faultless liability for defects of goods provided for by the EU Council Directive № 85/374/EEC of 25.07.1985[385] (hereinafter – the Directive). Since a person's liability also arises without fault, the injured party must prove (1) the existence and amount of the damage, (2) the existence of a defect in the product, and (3) the causal link between the defect and the damage (Art. 4 of the Directive). Similar provisions are contained in Article 1095 of the Civil Code.

The Directive also provides for conditions of exemption from liability. The most interesting case is the following: the manufacturer is exempted from liability if, at the time the product was put into circulation, the level of scientific and technical knowledge did not allow to detect the presence of a defect or such defect is caused by the peculiarities of the product's design (Article 7 (e) and (f) of the Directive). At the same time, the extension of this exception to medical AI systems leads to the inappropriateness of the application of this tort: the registration of the algorithm as a medical device means that the system complies with the quality and safety requirements. Thus, it is presumed that the manufacturer could not have detected the defect at the stage of putting the AI product into circulation.

Detecting design flaws in the algorithm can also be a serious problem. It is extremely difficult to distinguish between normal and defective behavior of the system: harm can occur as a result of improper operation or as a result of an error within the normal range[386]. In the case of medical AI, the situation is further complicated by the following factors:

— medical intervention implies a natural risk of harm, which is accepted by the patient on the basis of informed consent («justified harm» in the terminology of Art. 24 of the Oviedo Convention of 1997, Sec. 3 of Art. 1064 of the Civil Code).;

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[384] Mosechkin I.N. Op. cit. P. 469.

[385] Directive (EU) № 85/374/EEC of 25.07.1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products // Offic. J. of the Europ. Union. Ser. L. 1985. Vol. 28, L210. P. 29-33.

[386] Nikitenko S.V. Civil-legal responsibility for the harm caused by artificial intelligence. P. 24.

— there are several ways to solve any clinical problem, the effectiveness of each of which cannot be absolute (even highly qualified specialists cannot guarantee success in treating a complex or previously unknown pathology);

— it is impossible to fully predict the effects, consequences and risks of therapy, as well as to identify all possible abnormalities and their causes based on the results of diagnostics;

— confusion between AI defect and medical malpractice, which is expressed through the difficulty of identifying the main cause of harm: whether the harm resulted from the incompetence of the physician, who relied on the results of a high-precision algorithm[387], or from a defect in the program.

Applying the concept of liability to cases of harm in medical practice is thus likely to lead to an imbalance due to the unnecessary expansion of the scope of liability of manufacturers, who, unlike physicians, will be held liable for virtually any harm caused by algorithms, even if the probability of system error was significantly lower than that of a human expert.

The functional purpose of medical AI, which is currently used to support medical decision-making (as a so-called MDSS), is also left unaccounted for. All clinical decisions made by the AI are subsequently evaluated by the physician, who becomes legally responsible for the consequences of such a decision. Thus, there will be no causal link between the system defect and harm: the main cause will be the incompetence of the specialist who did not reject the clinical decision made by the algorithm. Logically, in this situation, there is no rational basis for holding the manufacturers who properly registered the AI systems liable.

We believe that manufacturers can be held liable in a limited number of cases. If there is an obligation to register the systems as medical devices, it would be reasonable to hold manufacturers liable in the case of unregistered algorithms, failure to comply with the requirements of technical and operational documentation, and failure to fulfill the obligation to maintain the system. In the sphere of retail sale, an additional obligation is imposed on the manufacturer to provide the consumer with all necessary information about the product, conditions of its operation and maintenance, for violation of which the person should also be held liable. At the same time, the said basis of liability should not be interpreted broadly: it is impossible to predict all risks and threats of uncontrolled development of AI. Therefore, within the framework of the relations under consideration there should always remain the sphere of exclusive responsibility of the user who agreed to such a risk.

Let us also consider several positions regarding potential subjects of liability. We believe that a medical organization, which independently decides to implement AI, accepts it in accordance with the procedure stipulated by law[388], and also organizes training of its employees in the rules of working with

[387] Ivanova A.P. Op. cit. P. 155.
[388] Kiseleva A.Y. Op. cit. P. 34.

such systems[389], should be considered as an separate subject of responsibility. It is proposed to hold a medical organization liable with the right of such an organization to recover losses from other guilty parties by way of regress[390], for example, from the employee who incorrectly used the AI. This mechanism can be used already now (its basis is laid, in particular, in Art. 1068 of the Civil Code).

The significant influence of the training process on the algorithm's performance leads us to the necessity to include in the circle of subjects of responsibility the persons who provide AI training, which is also mentioned in paragraph 56 of EU Resolution № 2015/2103. Improperly organized training (use of insufficient data, unrepresentative datasets, etc.) can lead to a significant decrease in the efficiency of the algorithm, which is clearly demonstrated by the example of the Watson for Oncology system.

Concluding the analysis of existing liability concepts, we note a fairly widespread proposal to introduce a mechanism of liability insurance for damage caused by AI. In this case, compensation for damage in such a case is carried out from a specially created insurance fund replenished by contributions from the use of AI systems[391]. This mechanism can be used in conjunction with other liability concepts, for example, with the manufacturer being held vicariously liable in the event that the insurance indemnity proves insufficient[392].

The advantage of this approach is the guarantee of protection of the interests of the victim[393], who is relieved of the need to prove the full corpus delicti. The insurance company, in turn, will have sufficient financial, administrative and time resources to carry out an expert examination and find out all the causes of what happened. The introduction of a liability insurance mechanism is supported in paragraph 57 of EU Resolution № 2015/2103 due to the impossibility of identifying a specific person responsible for the damage caused by an advanced AI system. It should be noted that the liability insurance mechanism, despite its convenience and efficiency, in our opinion, gives rise to new problems related to the definition of policyholders and beneficiaries, insurance events and recourse rules. The introduction of compulsory insurance of liability for damage caused by AI seems to be a process beyond the control of law enforcement also due to (1) the lack of clear criteria of the level of autonomy sufficient for the emergence of the obligation to insure, (2) the absolute diversity of algorithms in terms of their number, functions, intended purpose, and the degree of potential «harmfulness». Therefore, the introduction of a liability insurance mechanism for AI owners seems to be premature at present.

Analysis of the existing theory and legal regulation has shown the absence of any unified approach to solving the problem of tort liability for harm caused by AI[394] and the range of subjects of

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[389] Ivanova A.P. Op. cit. P. 156.
[390] Varyushyn M.S. Op. cit. P. 21.
[391] Filipova I.A. Op. cit. P. 87.
[392] Malyshkin A.V. Op. cit. P. 453.
[393] Mamychev A.Y. Modern doctrinal-legal and ethical problems of development and application of robotic technologies and artificial intelligence systems (on the example of autonomous uninhabited underwater vehicles) / A.Y. Mamychev, Y.V. Gaivoronskaya, O.I. Miroshnichenko // Territory of New Opportunities. Vestnik VGUES. 2018. № 3. P. 146-147.
[394] Magrani E. Op. cit. P. 7.

liability. We believe that each participant of AI-relations has objective grounds to be held liable depending on the circumstances of each specific case, taking into account: (1) the possibility to influence the work of the algorithm to prevent harm or reduce its consequences, (2) passing quality control, (3) compliance with the requirements set forth in sources of law, technical regulations, (4) as well as technical and operational documentation, (5) the existence of obligatory (labor or civil law) relations between the responsible person and the operator.

The specifics of using AI in medicine should also be taken into account. The very fact that the algorithm is registered as a medical device already determines its compliance with quality and safety requirements. In addition, a clear statement of the algorithm's characteristics, rules of its operation and maintenance, as well as the inclusion in the supporting documentation of a plan for managing changes that may arise in the process of using the algorithm, will help to delimit the areas of responsibility of the participants in the AI relationship.

The principle of risk management also acquires «medical» specificity. Thus, to ensure increased protection of patients' life and health, the principle of personal responsibility of physicians for decisions made by AI should be enshrined, within the framework of which (1) no clinical decision made automatically can be final without verification by a specialist[395], (2) who, when making such a decision, is legally responsible for its consequences, including the harm caused[396]. In this case, in our opinion, the medical specialist should be liable by way of presumption, since the patient is a weak party in the framework of legal relations related to the provision of medical care, and has limited ability to establish the signs of the corpus delicti. Accordingly, the doctor may be exempted from liability if he proves that the harm was caused by the consent of the patient himself or occurred within the natural risk, which is characteristic of the chosen type of medical intervention.

Based on the results of the above analysis, we can form the main provisions of a special tort liability for harm to life and health caused by a medical AI system. Such a special tort should be based on the combination of the elements of general tort and the principle of risk management in cases where the fault of a particular person cannot be established or such harm is not unlawful because the registered algorithm worked properly in accordance with the technical and operational documentation.

The basis for liability should be considered the infliction of harm as a result of non-compliance by a participant in an AI-relationship with the requirements imposed within the framework of control over the circulation of medical devices, as well as the rules of production, transportation, storage, sale, operation, maintenance and decommissioning of intelligent systems, which are set out in regulatory legal acts, technical and operational documentation or are assumed as part of good faith behavior. In turn, a

[395] Varyushin M.S. Op. cit. P. 21; Borisov D.N. Op. cit. P. 29.
[396] Kamensky S. Op. cit. P. 9; Chelysheva N.Y. Op. cit. P. 21.

medical specialist is held liable on the basis of the principle of risk management if the following conditions are met[397]:

— the rules of production, transportation, storage, sale, operation, maintenance and decommissioning of the algorithm are not violated;

— the causer of harm and the victim acted in good faith, i.e. by their actions did not contribute to the infliction of harm or worsening of the consequences of its infliction, and could not foresee or prevent the infliction of harm;

— the causer of the harm (physician) has assumed the risk of harm under the professional presumption;

— the victim did not accept the risk of harm as part of the informed voluntary consent procedure for medical intervention.

We believe that the presented concept of tort liability for harm caused by a medical algorithm takes into account to the greatest extent the interests of all participants of AI-relations in the field of health care, contributes to the protection of patients' rights while maintaining an acceptable level of freedom of scientific research and commercial use of their results. In our opinion, this approach can serve as a basis for the creation of international legal regulation of liability for harm caused by AI, which is practically absent at the moment.

[397] Nikitenko S.V. Concepts of tort liability for harm caused by artificial intelligence systems. P. 171-172.

CHAPTER 4. STATE COOPERATION IN THE DEVELOPMENT AND USE OF ARTIFICIAL INTELLIGENCE FOR MEDICAL PURPOSES

§ 4.1. Directions and forms of international legal cooperation in the field of artificial intelligence for medical purposes

The implementation of international cooperation, being a principle of both international law in general and international medical law and international legal regulation of the achievements of STP – in particular, plays a crucial role in regulating the use of AI in the field of medicine. The special importance of cooperation is emphasized in the preamble to the WHO Constitution, which states that «the health of all peoples is a fundamental factor in achieving peace and security and depends on the fullest cooperation of individuals and nations». As Prof. L.A. Lunz points out, close interstate cooperation is also necessary to ensure the unification of law[398] – a process that is extremely relevant at present, when the legal regulation of AI becomes the subject of haphazard and uncoordinated international rulemaking.

Due to the lack of comprehensive international legal regulation of the use of AI in medicine, we can highlight only a few of the most important areas of interstate cooperation. At the moment, there are active discussions on ethical and legal principles of regulation, quality standards and safety of intelligent technologies[399]. However, only in a few sources of international law will we see attempts to enshrine specific legal norms that can be implemented in practice (with the exception of technical regulations, which are generally not sources of international law).

In this context, we should point out that the level and activity of international cooperation will inevitably depend on the current geopolitical situation and the good faith of subjects of international law in interpreting and fulfilling their international obligations, first of all, the universally recognized principles and norms of international law. In this regard, special attention should be paid to the enshrinement of guarantees of States aimed at providing:

— the interpretation and application of the provisions of international treaties in the light of their object and purpose, i.e. the proper implementation of the provisions of the Vienna Convention on the Law of Treaties of 1969 in order to prevent abuse by unscrupulous subjects of international law;

— national security and protection of the foundations of the constitutional order, morality, health, rights and legitimate interests of other persons, ensuring national defense and security of the state. The achievement of this goal is largely facilitated by Article 79 of the Constitution of the Russian Federation, which enshrines the conditions for non-execution of decisions of international bodies taken

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[398] Luntz L.A. Course of international private law : in 3 vols / L.A. Luntz. M.: Spark, 2002. P. 31-34.

[399] Ranschaert E.R. Artificial intelligence in medical imaging / E.R. Ranschaert, S.P. Morozov, P.R. Algra. Cham: Springer International Publishing, 2019. 373 p.

on the basis of the provisions of international treaties of the Russian Federation in their interpretation contrary to the Constitution of the Russian Federation.

In turn, it should be noted that eradicating the policy of double standards in international cooperation in the field of human rights and making it non-politicized, equal and mutually respectful is currently the direction of Russia's foreign policy (paragraph 47(3) of the Concept of Foreign Policy of the Russian Federation). Thus, the question of the forms and expediency of international cooperation, the effectiveness of existing or potential international legal regulation in the current geopolitical situation belongs to the sovereign sphere of discretion of each state and is a foreign policy issue, which is reflected in the legal policy of the State.

There is a tendency in the formalization of relations in the AI-sphere, which are currently predominantly excluded from the control of the legislator, which naturally deprives the participants of such relations of legal protection. Increased legal certainty through more detailed regulation of the legal regime of intellectual technologies will lead to the elimination of barriers to cross-border trade, growth of the digital economy and acceleration of the STP[400]. The main goal of international cooperation in AI should be to minimize the risks of harm and human rights violations that uncontrolled development of dual-use technologies can lead to[401], with unconditional guarantees to ensure the national security of states, which is especially important for the Russian Federation in the current geopolitical situation.

As we noted earlier in Chapter 3 of the dissertation research, ensuring the safety of the use of AI systems is achieved through the harmonization of information-exchange processes and data format, the establishment of general principles for the admission of intelligent systems into civil circulation, as well as the development of an effective mechanism of liability. The safety of the use of medical AI, in turn, is ensured by improving the procedure for obtaining informed voluntary consent for medical intervention and establishing general rules to control the circulation of medical devices. For example, unification of technical and clinical testing procedures will ensure a single safety standard within an interstate organization or an integration association (which is the most likely). The harmonization of technical regulations (first of all, in the field of creation, operation and maintenance of algorithms), in turn, will ensure the compatibility of intelligent systems and information networks of states.

Development and improvement of the system of technical standards in general is one of the most priority areas of cooperation and international legal regulation of modern technologies, which was also emphasized by WHO, devoting to this issue a separate Resolution WHA66.24 of 27.05.2013[402]. In this

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[400] Bakhin S.V. Influence of New Technologies on Modern Private International Law. P. 106-138.

[401] Financial Markets, Insurance and Private Pensions: Digitalisation and Finance [Electronic resource] / OECD, 2018. 108 p. URL: http://www.oecd.org/finance/Financial-markets-insurance-pensions-digitalisation-and-finance.pdf (date of access: 30.05.2023).

[402] Standardization and interoperability in eHealth: WHO resolution of 27.05.2013 № WHA66.24 [Electronic resource] // WHO: [website]. URL: https://apps.who.int/iris/bitstream/handle/10665/151516/A66_R24-ru.pdf?sequence=1&isAllowed=y (date of access: 30.05.2023).

context, the previously mentioned draft EU Regulation on harmonized rules on AI from 16.05.2023, which is dedicated to the creation of a common legal regime for AI regardless of the sphere of its use, deserves close attention. The main goal of the project is to standardize the procedure for creating data sets, rules for ensuring transparency and accessibility of information about intelligent systems, control over algorithms, as well as requirements for their accuracy, reliability, security, etc., which indicates the main trends in the legal regulation of the considered area.

The efficiency of AI systems has a direct correlation with the volumes of available information, as well as the scope and speed of communications between different elements of the digital infrastructure. Accordingly, increasing the level of information openness, reducing the amount of restricted information[403] and convergence of transnational information exchange processes are criteria for «healthy» international legal regulation and cooperation in the field of AI. For this reason, one should be cautious about the current trend of localizing data by establishing national restrictions on its cross-border movement[404]. We do not deny the expediency of establishing such restrictions to protect national interests and ensure the security of the state, especially in the geopolitical situation existing at the time of writing this study, but we point to the need to strike a balance between measures to localize data and measures to improve the existing information infrastructure and the protection measures applied[405]. The existence of a balanced system of transboundary data exchange with security guarantees for the participants of such exchange would equally ensure the achievement of the national interests of the state by improving, first of all, the health care system[406].

An equally important area is international cooperation in the field of intellectual property. First of all, national treatment and most-favored-nation treatment should be established in the field of intellectual property – this approach, in particular, is implemented in the TRIPS Agreement of 1994. However, according to the fair comment of Prof. O.A. Gorodov, at present, attention should be paid to technical means of protection of rights to the results of intellectual activity, as well as to expand the use of so-called inclusive regulatory mechanisms, which allow to mitigate the exclusivity of the right holder's position in the conditions of modern information society. Examples of such measures include Creative Commons licenses, free software and alternative compensation, as well as compulsory licensing and

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[403] Gorodov O.A. Main directions of improvement of legal regulation in the sphere of digital economy in Russia. P. 8.

[404] Willems A. Op. cit. P. 238.

[405] Chander A. Breaking the Web: Data Localization vs. the Global Internet / A. Chander, U.P. Le // UC Davis Legal Studies Research Paper Series. 2014. № 378. P. 32–33; Willems A. Op. cit. P. 239.

[406] Analysing the risks of free cross-border data exchange and the measures needed to ensure national interests and information security of states is a topic for a separate and detailed study. In this paper, the author addresses only two categories of data – health data and technical information on the functioning of interoperable information systems and intelligent medical developments.

public domain regimes[407], each of which merits a separate study, as they serve the interests of both rightsholders and users in the context of the proliferation of information technologies.

Developing an efficient and safe AI algorithm requires a large amount of data. Intellectual property rights to datasets, usually authored by private developers, research groups and organizations, can prevent the creation of federated databases and make it difficult to use individual datasets. In this regard, AI developments will certainly be facilitated by (1) further encouraging the distribution of medical databases by their copyright holders under Creative Commons licenses[408] and (2) creating digital platforms to host datasets under uniform terms of use (along the lines of Kaggle, Papers with Code, Google Dataset Search, etc.).

However, given the financial and time costs of preparing databases, the economic interests of right holders should also be sufficiently safeguarded. This goal, in particular, will be facilitated by the recognition of data sets as objects of copyright and related rights, which corresponds to the existing international legal practice (Art. 10(2) of the TRIPS Agreement of 1994, Art. 5 of the WIPO Copyright Treaty of 1996 and EU Directive № 96/9/EC of 11.03.1996 «On the Legal Protection of Databases»[409]).

It is also important to harmonize the positions of States on the restriction of intellectual property rights to safeguard vital public interests (e.g., public health, public order and morality), to prevent the abuse of intellectual property rights, and to protect competition. Bringing such restrictions to uniformity will ensure legal certainty in the regulation of relations related to the creation and exchange of AI technologies. Of interest in this context is Art. 27(3) of the TRIPS Agreement of 1994, according to which states may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals for the protection of public health, which naturally covers the use of medical algorithms. At the same time, international legal regulation does not contain exceptions for the free use of AI systems and databases for scientific purposes, although such an exception is enshrined in Russian legislation (Art. 1274 of the Civil Code[410]). We believe that in order to increase research activity and quality of intellectual technical solutions, the states should fix the cases of using datasets for training algorithms as a case of free use of this result of intellectual activity.

Finally, in the field of AI, technical and financial cooperation between states is at the forefront, without which the creation of secure algorithms will be extremely difficult. Such cooperation should

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[407] Gorodov O.A. Main directions of improvement of legal regulation in the sphere of digital economy in Russia / O.A. Gorodov, M.A. Egorova // Law and Digital Economy. 2018. № 1. P. 10-11.

[408] Creative Commons licenses [Electronic resource]: public licenses for the use of copyright objects by an unlimited number of persons // Creative Commons: [website] / Creative Commons Corporation. Mountain View, 2002. URL: https://creativecommons.org/licenses/ (date of access: 30.05.2023).

[409] Directive (EU) № 96/9/EC of 11.03.1996 on the Legal Protection of Databases // Offic. J. of the Europ. Comm. Ser. L. 27.03.1996. Vol. 39, L77. P. 1-42.

[410] Computer programs (or «computer programs» in the terminology of the Civil Code) are protected as literary works according to Art. 1259 of the Civil Code. In this connection, the cases of free use of works provided for by Art. 1274 of the Civil Code also apply to software, including software with AI elements.

include assistance in the development of legal regulation in the field of intellectual property protection, the prevention of abuse (including the suppression of anti-competitive practices) and the strengthening of links between national authorities with competence in these areas. In the field of medicine, cooperation aimed at organizing the sharing of innovative AI developments and linking clinical databases is also of great importance.

The implementation of the principles of international health law and the framework for the regulation of STP, specified in § 1.1 of the dissertation, implies strengthening international cooperation between developed and developing states in order to reduce the technological gap between them, as well as to increase the coverage of the population with health services and improve their quality. This gap creates a risk of monopolization of international legal regulation of relations complicated by AI by a few most developed states, which excludes other sovereign participants from the norm-making process. Moreover, we will not find unity among the «monopolists» either: while some seek to liberalize the digital economy (USA), others take positions of more active state intervention (EU) or protectionism and control (China)[411]. Without addressing the issue of the advantages of implementing the latter approach in an unstable geopolitical environment, we would only note that the very fact that there are fundamentally opposing positions is an obstacle to the development of a unified international legal regulation. Undoubtedly, norms in this area should be developed taking into account international and national security, which is especially important for the Russian Federation in the current geopolitical situation.

In order to bridge the scientific and technological gap and increase the provision of high-tech medical care, States should share law enforcement experience, establish preferential legal treatment for innovative developments in developing countries, as well as improve digital literacy and promote the development of information and communications technology infrastructure, particularly through the expansion of broadband Internet access. In the health sector, great attention should be paid to the development of national information systems and ensuring their interaction with similar systems of other states, including through the development and implementation of common international standards for the format and processing of clinical data.

The need for legal regulation of relations related to the use of AI in medicine, pharmacology and biology raises the question of the sources of international law most appropriate to the specifics of the subject of regulation. The high dynamics of social relations caused by STP determines the need to choose legal tools that ensure the flexibility of regulation (through the possibility of rapid adoption of new acts or amendments to them) and, at the same time, its stability (through the consolidation of a system of legal principles).

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[411] Willems A. Op. cit. P. 232.

Sources of law containing international obligations (conventions, covenants, etc.) are not sufficiently effective for the regulation of AI relations. Harmonization of the will of sovereign power actors to create binding international legal norms is achieved through a laborious process, especially with regard to issues that traditionally fall within the sphere of discretion of states (which, in turn, includes control over the circulation of medical devices). The drafting, negotiation and enactment of an international treaty often takes a long period of time, which can be years. Moreover, even if the text is agreed, States may not agree to be bound by such an international treaty. These factors indicate the low effectiveness of this source of international law in regulating certain advances in STP that require prompt action.

At the same time, as it was mentioned in § 1.1 of the dissertation research, the formation of a universal international legal framework to regulate relations in the field of health protection and STP, which will allow timely response to the new challenges of the problem caused by technological development. The fixing of a number of cardinal normative provisions in an international treaty will significantly increase the legal certainty of regulated relations and the safety of the use of STP achievements. However, the creation of such an international treaty will inevitably raise serious difficulties related to technological inequalities and the different capacities of states to ensure equal living standards, which will take a long time to overcome. Without denying the need for such an international health treaty, we believe that such a source of international law is nevertheless hardly suitable for regulating private aspects of technology use.

International custom is also not adapted to the ordering of relations in the field of modern technology: during the time during which the custom will be formed, technical achievements may become obsolete and cease to be used in practice. The emergence of new technologies will start the process of formation of custom anew. In addition, the multivariant nature of customary rules of behavior and their brevity make it difficult to use customary law in the sphere of STP, where clear consistency and formal definiteness are required, especially in terms of technical regulation[412]. Legal custom can be used mainly to fill the «legal vacuum», and the customary legal norms of sufficiently definite content can be subsequently enshrined in the sources of law.

Decisions of international organizations are of great importance for regulating the results of STP, the advantages of which are: speedy agreement of the text of the normative act, simplified procedure for their adoption and amendments. Decisions of international organizations allow for detailed regulation of a certain mechanism, procedure or legal institution. At the same time, international organizations are not always vested with the power to adopt binding decisions. Moreover, even in the presence of such a

[412] Bakhin S.V. Influence of New Technologies on Modern Private International Law. P. 106-138.

right, participating States prefer to turn to legal instruments that do not impose international obligations on them.

In our opinion, the adoption of an international legal act containing formally defined and enforceable obligations of states in the field of the use of AI (including in the field of medicine) is unlikely in the near future, which is due to the objective reasons we mentioned in § 1.1 of the dissertation research (each state has its own level of financial, organizational, technical and personnel support of the national health care system). Nevertheless, we should not underestimate the role of advisory norms in the regulation of international relations: the complexity and novelty of the subject of regulation in the absence of a comprehensive legal regime of modern technologies causes the subjects of international law to choose non-binding normative acts as a basis for the development of domestic legislation, international agreements or binding decisions of international organizations. The creation of an international model law, declaration and international standards (similar to ISO standards) seems most likely. Despite the non-binding nature of the norms contained in these acts, their incorporation within the framework of integration associations and national legal orders is inevitable: this process is already observed in the area of unification of some procedures for quality control of medical AI systems, as well as in general – in terms of implementation of the principles of AI regulation.

The analysis of norm-setting activities of interstate entities shows that integration entities are currently particularly active in terms of AI regulation. For this reason, in the short term, the solution of many issues in the field of AI use, including in medicine, will find its consolidation within the framework of integration entities (EU, EEU), an example of which is the previously mentioned draft EU Regulation on harmonized rules on AI dated 16.05.2023 («AI Act»).

In conditions of high dynamics of social relations development, self-regulation plays a special role. According to O.A. Gorodov, «specific regulation should be established by the participants of digital ecosystems»[413], in this regard, sovereign participants in international relations should ensure the possibility of fulfilling the obligations assumed by non-sovereign actors (for example, within the framework of ISO, IEEE or NEMA standards). However, self-regulation has its own limits due to the operation of principles and imperatives of international law, as well as international obligations assumed by sovereign actors, which is the essence of the principle of limited self-regulation under transnational law[414].

In addition to the enshrinement of norms in the sources of international law, the implementation of international legal norms in the field of AI requires an effective mechanism to monitor compliance. As outlined in WHO's Draft Global Strategy for Digital Health 2020-2025, establishing sustainable and robust international governance structures and regulatory mechanisms is one of the main challenges of

[413] Gorodov O.A. Normative regulation on digital markets as a means of protecting national interests / O.A. Gorodov, M.A. Egorova // Law and Digital Economy. 2019. № 1. P. 5-6.

[414] Galenskaya L.N. Legal regulation of transnational relations : a monograph / L.N. Galenskaya. SPb.: SPbU Publishing House, 2022. P. 68.

digital health regulation. At the same time, relations related to the use of AI in medicine are currently not actually considered by international bodies and organizations for the purpose of creating legally binding norms for the states, and there is no coordination of existing rule-making at all.

At the moment we will see that some issues of AI use (including medical applications) are being implemented in a number of international interstate (WHO, UNESCO, ITU, WIPO, WTO) and non-state organizations (WMA, CIOMS, ISO, IMDRF), by a special commission within the framework of the integration entity (EU), as well as by many individual states[415] (Russia, USA, UK, China, Canada, Israel, Kingdom of Saudi Arabia, etc.) and non-governmental organizations (NEMA, IEEE, etc.). This decentralization, coupled with haphazard and uncoordinated rulemaking, only exacerbates the challenges posed by the proliferation and adoption of AI developments.

For this reason, it is currently relevant not to establish a new specialized international organization[416] or to expand the competence of existing associations, but to create an international body to coordinate normative and law enforcement activities in the field of the use of AI technologies on a non-discriminatory basis. In our opinion, it is advisable to establish a special body within the UN (in accordance with para. 2 of Art. 7 and 22 of the UN Charter), similar in structure, powers and operating procedures to the UN Commission on International Trade Law, which would be entrusted with the function of coordinating international legal, integration and domestic regulation of AI.

[415] Nikitenko S.V. International Legal Regulation of Artificial Intelligence: Analysis of the Current State and Prospects of Development. P. 154.

[416] Willems A. Op. cit. P. 236.

§ 4.2. Harmonization of clinical data format and information exchange processes

AI requires large amounts of data, both labeled and unstructured, for training and tuning. The more training data an algorithm processes, the more accurate its results will be[417]. The growth of the algorithm's efficiency depending on the amount of processed data is clearly depicted on the example of ROC curve [418] (cf. Appendix D). It is important to realize that AI is not «smart» from the moment its predictive model is created: without proper training, the potential of any algorithm will not be realized, making data collection one of the pain points in AI development[419].

Formation of medical databases is a labor-intensive, time-consuming and expensive process. In this regard, some organizations choose to use non-intelligent systems, which can be put into operation immediately after purchase without additional costs, although at the expense of efficiency[420]. The lack of unified clinical databases and information systems (local, national and transnational) also leads to increased time of care, repeated trials and abuse by medical personnel.

Thus, the issue of formation of medical databases of proper volume and quality, a unified procedure for their consolidation and interaction is of fundamental importance for the development of AI, its safe use and ensuring the effective realization of the right to medical care[421]. The technical incompatibility of information systems necessitates the convergence of national legal orders, especially in terms of technical regulation. Harmonization of data format and information exchange processes is also indicated by WHO in Resolutions № WHA69.24 of 2016 and № WHA71.7 of 2018.

The view most strongly supported by researchers is the creation of comprehensive databases that bring together information about various aspects of a patient's health from available sources[422]. It is noted that such bases have great potential for the development of AI, which, based on the analysis of heterogeneous information, will be able to build comprehensive forecasts based on the interconnection of different areas of medical knowledge and human life. An example of such a database is the UK Biobank, which brings together a wide range of clinical information (MRI scans, blood tests, etc.) from

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[417] What is IoT and what you should know about it [Electronic resource] // HABR.COM: information resource for IT-specialists «Habr». 2021. March 29. URL: https://habr.com/ru/company/otus/blog/549550/ (date of access: 30.05.2023); Towards more Accessible Precision Medicine: Building a more Transferable Machine Learning Model to Support Prognostic Decisions for Micro- and Macrovascular Complications of Type 2 Diabetes Mellitus [Electronic resource] / E. Kim [et al.] // Journal of Medical Systems. 2019. Vol. 43. № 7. doi: 10.1007/s10916-019-1321-6; Ivanova A.P. Op. cit. P. 157.

[418] Dyakonov A. AUC ROC (area under the error curve) [Electronic resource] // DYAKONOV.ORG: personal blog of Alexander Dyakonov. 2017. 28 July. URL: https://dyakonov.org/2017/07/28/auc-roc-площадь-под-кривой-ошибок/ (date of access: 30.05.2023).

[419] Bitherman O.E., Vorobyev S.M., Komarov S.A. Legal bases for ensuring national projects in the field of development of artificial intelligence in the Russian Federation / O.E. Bitherman, S.M. Vorobyev, S.A. Komarov // Theory of State and Law. 2023. № 2 (31). P. 27.

[420] Ivshin A.A. Op. cit. P. 134.

[421] Chelysheva N.Y. Op. cit. P. 21.

[422] Ibid. P. 19.

more than 500,000 people[423]. However, no comprehensive databases have been created globally. Among the publicly available sources, we find only many specialized databases containing clinical information in certain areas of medical practice at the local level. However, the unification of such databases is hardly possible in practice due to the different order of their formation, data markup, lack of data verification system and the presence of copyright and/or related rights to the relevant data sets.

In this regard, the most realistic alternative to the extensive method of creating complex databases is the development and implementation of universal standards of compatibility and access to databases and information systems of different levels, including the creation of protocols that provide a single platform for searching for certain information or datasets in databases. The greatest progress in this area has been made by Integrating the Healthcare Enterprise International, a non-profit organization that specializes in developing IHE profiles that integrate the many standards and protocols associated with medical data processing[424].

As an example, the IHE XDS (Cross Enterprise Document Sharing) profile contains standards for cataloging and sharing data from patient records between healthcare organizations. In particular, this profile provides uniform rules for maintaining electronic medical records, as well as rules for retrieving relevant clinical information[425]. Unimpeded access to such data from anywhere and at any time can be provided by the WADO (Web Access to DICOM Objects) network protocol, which operates on the basis of a common Internet browser[426].

Thus, the formation of complex databases necessary for effective AI training is possible in two ways: extensively – through the unification of databases into a single data bank, or intensively – through the creation of unified protocols for the interaction of information systems and the introduction of a unified database search platform. In our opinion, the most expedient is the development of the second group of standards, which we propose to base on the IHE profiles already developed by specialists.

The quality of data is as important for AI as the quantity of data. Invalid data can lay down a structural deviation in the work of the entire algorithm. A uniform data format is also important for the normal operation of the system[427] – poorly structured and heterogeneous data cannot be processed or

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[423] UK Biobank [Electronic resource] : UK citizens' biomedical database / UK Biobank Limited. [Stockport], 2022. URL: www.ukbiobank.ac.uk (date of access: 30.05.2023).

[424] Integrating the Healthcare Enterprise [Electronic resource] : official website of IHE International – a non-profit organization dedicated to the interoperability of health information systems and exchange processes / IHE International. [Oak Brook, 2022]. URL: https://www.ihe.net/ (date of access: 30.05.2023).

[425] Medical imaging document sharing solutions for various kinds of healthcare services based on IHE XDS/XDS-I profiles [Electronic resource] / J. Zhang [et al.] // Proceedings of the SPIE – The International Society for Optical Engineering. 2014. Vol. 9039. doi: 10.1117/12.2042970.

[426] Pereverzev M. IS in healthcare need integration [Electronic resource] // CNEWS.RU: Internet edition «CNews» about high technologies. 2013. 25 June. URL: https://www.cnews.ru/reviews/it_v_zdravoohranenii/articles/is_v_zdravoohranenii_nuzhdayutsya_v_integratsii (date of access: 30.05.2023).

[427] The use of artificial intelligence in public health care: the experience of validation of the artificial intelligence algorithm in medical organizations in the COVID-19 pandemic / I.A. Blokhin [et al.] // Monitoring of public opinion: economic and social changes. 2021. № 1. P. 275.

will significantly reduce the efficiency of the algorithm. First of all, as a result of accumulation of a large amount of data and their processing by linear methods, a number of technical problems appear.

Thus, the formation of voluminous databases leads to the problem of providing storage of such data and lack of physical memory carriers. The most common way to solve this problem is data compression, which is especially relevant for diagnostic images[428]. However, a high level of compression can lead to the loss of significant information, so steps have already been taken in this area to develop optimal compression standards, which also differ depending on the application (e.g. DICOM protocol). Similar is the case with a common way to improve the quality of diagnostic images, such as changing their sharpness and/or contrast to minimize noise. There are also no standards setting thresholds for such conversion. Unfortunately, few agencies pay attention to this aspect of image processing[429].

Validation of datasets is relevant for training, validation and test datasets. Despite the undoubted importance of forming correct datasets for the development of an efficient algorithm, there are no unified data validation procedures available. To a large extent, the guarantee of the correctness of datasets at the moment is the authority and qualification of the dataset compilers themselves. In our opinion, in the case of medical AI systems, there is no need for international unification of the data validation procedure, since the quality of the algorithm is checked within the framework of control over the circulation of medical devices. Registration of the algorithm as a medical device will indirectly mean the correctness of the datasets used for training. At the same time, we do not deny the expediency of introducing a procedure for validating datasets, as this is in line with the general principle of safe use of AI.

Finally, unification of data format and information exchange processes is of great importance. The interaction of medical AI devices and software, clinical databases, and their operators is carried out within the framework of a certain information system that unites these components on the basis of unified information exchange processes and compatibility rules. The effective operation of such a system is unthinkable without the application of uniform rules that relate to the format of markup of medical data, the procedure for identifying patients and maintaining medical records, confidentiality measures, protocols for interaction of components of the hardware and software complex, etc.[430]

The greatest degree of unification has been achieved in the field of visual medical data, where the DICOM (Digital imaging and communication in medicine) data generation, storage and transmission standard developed by the National Association of Electronic Equipment Manufacturers (NEMA) back in 1993 (version 3.0) is in force. This standard is used by most medical organizations around the world, including Russia, where the national standard GOST R ISO 12052-2009 «Health Informatization.

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[428] 320-slice CT neuroimaging: initial clinical experience and image quality evaluation / E. Siebert [et al.] // The British Journal of Radiology. 2009. Vol. 82. P. 561-570.

[429] Morozov S.P. Review of the current state and basic requirements for PACS-systems / S.P. Morozov, M.O. Pereverzev // Physician and Information Technologies. 2013. № 3. P. 24.

[430] Morozov S.P. Op. cit. P. 19.

Digital images and communication in medicine (DICOM), including document and data management»[431], identical to the international standard ISO 12052:2006[432], which regulates the procedure for the use of the DICOM standard by medical organizations. Implementation of the DICOM standard ensures interoperability of various systems and technical solutions, including those related to the use of AI, by setting requirements for virtually every stage of clinical data processing, from image creation by a diagnostic device to uniform requirements for data security protocols.

Accumulation and transmission of medical images, in turn, is based on the information system PACS (Picture Archiving and Communication System), which provides interconnection between all diagnostic devices included in the system (usually within one medical organization), data storage on a separate server and data transmission from devices to the server, as well as from the server to the device or to another information system[433]. PACS is a generic definition for information systems, along with which are also distinguished: Laboratory Information System (LIS), Policy and Procedure Management System, Radiology Information System (RIS), and so on. The term Hospital Information System (HIS) is sometimes used as a generic term for such medical information systems.

Regardless of the level and scale of the information system, the availability of a well-functioning mechanism for receiving, classifying, storing and transmitting clinical data will significantly improve the efficiency and accuracy of medical care, prevent cases of double examination[434] and, thus, reduce the burden on medical staff by up to 80%[435], which is achieved solely by optimizing information processes[436] without taking into account the effect of AI application. This fact additionally indicates the need for standardization of information exchange processes.

At the same time, we do not find a single international standard for hospital information systems, except for the established DICOM and PACS bundle, which allows us to assert the need to unify information exchange processes in other spheres of medical activity. We believe that the DICOM protocol can serve as a prototype for the formation of other standards of information interaction within the framework of medical care. In turn, the transboundary nature of information exchange processes necessitates the development of an international technical regulation.

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[431] GOST R ISO 12052-2009. Health informatization. Digital images and communication in medicine (DICOM), including document and data management [Electronic resource] ; introduced 2010-07-01 // Reference legal system «Codex». Moscow, 2010. URL: https://docs.cntd.ru/document/1200081641?section=text (date of access: 30.05.2023).

[432] Health informatics — Digital imaging and communication in medicine (DICOM) including workflow and data management: ISO 12052:2006, published Nov. 2006 [Electronic resource] // ISO: [website]. URL: https://www.iso.org/standard/43218.html/ (date of access: 30.05.2023).

[433] Sechenov P. PACS-server with his own hands [Electronic resource] // HABR.COM: information resource for IT-specialists «Habr». 2013. 10 September. URL: https://habr.com/ru/post/193134/ (date of access: 30.05.2023).

[434] Boochever S.S. HIS/RIS/PACS Integration: Getting to the Golden Standard / S.S. Boochever // Radiology Management. 2003. Vol. 26. № 3. P. 16-24.

[435] Change in process management by implementing RIS, PACS and flat-panel detectors / H. Imhof [et al.] // Radiologe. 2002. Vol. 42. № 5. P. 344-350.

[436] Morozov S.P. Op. cit. P. 21.

The basis for the currently missing international legal regulation in this area can be normative acts developed by the professional community. We should not neglect the experience of foreign associations of specialists, since most medical devices and information processes have a common technological basis, which is confirmed by the active use of the DICOM standard. Manufacturers of medical devices, first of all, are themselves interested in standardization, as it facilitates entry into foreign markets of medical devices and software, which determines active self-regulation of the considered area.

Along with DICOM, such protocols as LOINC[437] (Logical Observation Identifiers Names and Codes), HL7[438] (Health Level 7) and the already mentioned IHE (Integrating the Healthcare Enterprise)[439], which lay down the rules for ensuring interoperability and integration of information systems, deserve attention. However, these standards are not widespread and are applied, as a rule, in English-speaking countries (first of all, the USA), where non-profit organizations that have developed such standards have been established.

Finally, one of the most important directions in the development of safe AI is the development of interoperable clinical information systems at different levels (local, regional, global). Currently, we can find examples of non-commercial databases containing marked-up datasets in a certain area of medical practice, as well as attempts to implement local and regional level information systems (see Appendix E for more details). However, such attempts are piecemeal, as the systems that have been created are not compatible with each other.

Thus, the issues of uniting databases and ensuring their compatibility within information systems of different levels, standardization of format, cataloguing and storage of clinical data, ensuring the uniformity of information exchange processes, as well as the introduction of publicly available systems for searching, indexing and quality control of data sets are of fundamental importance today. Similar areas of development are outlined in the federal project «Artificial Intelligence»[440], which is part of the National Program «Digital Economy of the Russian Federation»[441]. The implementation of the project involves, among other things, the introduction of vertically integrated medical systems; the creation of

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[437] LOINC [Electronic resource] : an international standard in laboratory classification and documentation / Regenstrief Institute, Inc. [Indianapolis], 1994-2022. Update date: 16.02.2022. URL: https://loinc.org/ (date of access: 30.05.2023).

[438] HL7 Standards [Electronic resource]: section of the Health Level Seven International website dedicated to standards in the field of medical information systems // HL7 International: [website] / Health Level Seven International. [Ann Arbor, 2007]. URL: https://www.hl7.org/implement/standards/product_section.cfm?section=14 (date of access: 30.05.2023).

[439] Integrating the Healthcare Enterprise. URL: https://www.ihe.net/ (date of access: 30.05.2023).

[440] Passport of the federal project «Artificial Intelligence» of the National Program «Digital Economy of the Russian Federation» Appendix № 3 to the protocol of the Presidium of the Government Commission on Digital Development, the use of information technologies to improve the quality of life and business environment from 27.08.2020 № 17 [Electronic resource] // Reference legal system «ConsultantPlus». Access mode: http://www.consultant.ru/.

[441] Passport of the national project «National Program «Digital Economy of the Russian Federation» : approved by the Presidium of the Presidential Council for Strategic Development and National Projects of the Russian Federation, Minutes of 04.06.2019 № 7 [Electronic resource] // Reference legal system «ConsultantPlus». Access mode: http://www.consultant.ru/

industry-specific datasets, unstructured and marked-up; and the establishment of a methodological center to coordinate the preparation of datasets.

Each of these areas should be regulated in the sources of international law and enshrined in the system of special international standards in the field of AI, which will ensure unimpeded cross-border exchange of technologies and data, as well as ensure the compatibility of hardware and software products worldwide, which is especially important in the era of globalization. Already existing DICOM, LOINC, HL7 protocols and IHE profiles can be used as a basis for international technical regulations[442].

[442] Morozov S.P. Op. cit. P. 19.

CONCLUSION

The development of modern information technologies has led to the transformation of all spheres of society, including health care. The complexity of social relations caused by the development of intellectual technologies and STP in general, as well as the emergence of new and transformation of existing activities lead to the need for their legalization. Remaining outside the legal framework, scientific discoveries and technical achievements can not only create, but also destroy, creating the risk of harm to life and health, systematic violation of rights, aggravation of the technological gap between developing and developed countries, as well as monopolization of the market of intellectual developments as well as abuse of the scientific potential of medicine for inhumane purposes by some unscrupulous subjects of international law.

The dual nature of the results of STP requires the establishment of special legal regulation, which should be aimed, on the one hand, at preventing and minimizing the negative consequences of technological development, on the other hand, at creating conditions for further development of STP, which generally follows from the functions of law as a regulator of social relations. At the same time, the development of uniform regulations in this area is complicated by technological inequality and different capabilities of states to implement scientific and technological achievements in practice. An additional factor complicating the regulation of the use of STP achievements is the rigidity of legal regulation: law, in most cases, does not have time to reflect changes in social relations caused by the rapid development of STP.

As a dual-use technology, AI requires addressing its own unique set of issues, such as: ensuring transparency of decision-making by algorithms, specifics of liability for harm caused by AI systems, etc. Medical application of intelligent technologies also has specifics of regulation (control over the circulation of AI systems at the post-registration stage, ensuring compatibility of data formats, information systems, etc.). At the same time, it is impossible to unambiguously define the range of issues subject to legal regulation due to the constant development of technologies. They can be regulated only after the legal problems caused by the implementation of STP achievements have been identified.

Due to the ever-increasing degree of involvement of algorithms directly in the process of medical intervention, the issue of ensuring the safety of AI use is becoming acute. At the same time, there is currently a lack of full-fledged legal instruments to regulate the use of AI in the field of medicine. In fact, the only legal act containing formally defined obligations in the field of regulating AI systems is EU Resolution № 2015/2103, which, however, is fragmentary, has regional specificity and does not address the issues of technology application in medicine. The analysis of the current international law shows the absence of special legal acts dedicated to the regulation of the use of algorithms for medical

purposes. Thus, there is a clear need to create a special international legal regulation to ensure the introduction of effective and safe AI into medical practice.

The subject of international legal regulation of the use of AI in the field of medicine includes relations related to the development, production, introduction into civil circulation, transportation, storage, sale, operation, maintenance and decommissioning of AI systems; relations of transboundary exchange of intellectual technologies and data; relations to ensure the safety of the use of AI in medical care and data processing. We can identify several priority areas of international cooperation in this area: the creation of a system of international standards for the development, introduction into civil circulation and operation of controlled and safe intellectual systems; ensuring the uniformity of information exchange processes and scaling of databases; improving the institution of joint ownership of intellectual property; reducing administrative barriers to cross-border trade and protection of the results of intellectual property.

The use of AI systems in medicine can be regulated at both national and international levels. Establishment of common international legal regulators can ensure interoperability of technical parameters, unification of requirements for AI safety, measures to minimize the risk of using dual-use technology to harm the national interests of states, human rights and freedoms as well as cross-border exchange of medical technologies and the results of their implementation in medicine, biology and pharmacology between countries interested in cooperation[443].

Coordination and harmonization of standard-setting of various participants of international relations in the field of health care in general is one of the most important tasks at present. It is necessary to start international standard-setting today, because further inaction will lead to the aggravation of the technological gap between developed and developing countries, impossibility of convergence of national legal orders, incompatibility of technical solutions developed in different countries and treatment methods associated with the use of innovations.

International legal regulation of the use of AI in medicine should certainly be based on the existing international treaties in the field of health care, which lay the legal foundations for the invasion of human health. However, despite their considerable volume, the norms of international law on health protection currently in force have not yet been gathered together into a separate branch of international law, which leads to the ineffectiveness of interstate cooperation and existing international legal mechanisms for resolving problems in the field of health care. The formation of a branch of international medical law is seriously hindered by the fact that legal norms concerning medicine and health care are

[443] Please note that under the current geopolitical situation, constructive international cooperation and cross-border data exchange between the Russian Federation and the states that fall on the List of Foreign States and Territories Committing Unfriendly Acts against the Russian Federation, Russian Legal Entities and Individuals, approved by the Order of the Government of the Russian Federation № 430-r dated 05.03.2022, is unlikely due to the existence of an increased risk of causing damage to national security for Russia.

scattered among various branches and institutions of existing international law. In order to create this branch of international law, it will be necessary to adopt a fundamental international treaty regulating the subject matter, principles and specifics of regulation of relations in the field of health protection.

When developing international legal regulation of relations in the field of health protection, we will inevitably encounter difficulties due to the different capabilities of states to ensure an equal level of their health care. Nevertheless, it is obvious that interstate relations in the field of health protection of people and nations should have a unified legal basis, allowing for international cooperation, the need to strengthen which was demonstrated by the dissemination of COVID-2019. In particular, based on a synthesis of existing international legal provisions, the principles to which the use of scientific and technological advances (including AI) in health care should be subject have been derived, namely: the responsibility of States for the health of their peoples; respect for human rights, fundamental freedoms and dignity, including the right to the enjoyment of the highest attainable standard of health; transition to universal health coverage; ensuring the safety of intrusion into the sphere of human health; cooperation of States, promotion of their own health care; and the protection of human health.

International legal regulation of the use of AI in the field of medicine should take into account the peculiarities of medical care, socio-economic consequences of digitalization, technical aspects of AI, legal principles of regulation of the achievements of STP and the legal basis for their use in health care, as well as objective regularities of the functioning of law as a regulator of social relations (its internal and external limits). The very totality of international legal norms regulating the use of intellectual technologies in medicine is inter-branch, therefore it cannot be singled out as an independent branch or legal institute of international law, but represents a set of separate legal norms within the framework of already existing international legal institutions and procedures that determine the specifics of the use of AI. Nevertheless, the analysis of existing legal and other normative acts of international, integration and domestic law allows us to generalize the following cardinal normative provisions, which can serve as a basis for special international legal regulation of the use of AI in general:

1. Principle of informed consent. Expresses the autonomy of the individual, who, based on information about the technology and guided by his or her own interests and experience, makes an informed and voluntary decision regarding the possibility and manner of interaction with AI, including the informed acceptance of the risk of negative consequences;

2. Principle of safe use. It assumes the adoption of special international, national and industry standards in the field of development, introduction into civil circulation and operation of intelligent systems, introduction of a system of public quality control of AI developments, ensuring information security, as well as a balanced and effective mechanism of responsibility distribution. In addition, within the framework of this principle it is supposed to ensure the protection of the algorithms themselves;

3. Risk management principle. It includes: assessment of security risks through monitoring of possible threats of harm to protected human rights and legitimate interests; assessment of security risks of AI systems themselves; minimization of detected risks; risk management based on the subject's consent. This principle should extend to the stage of AI development, which will prevent the emergence of algorithms that create an unreasonable risk of violating human rights and freedoms, causing harm to human life and health;

4. Transparency principle. This principle is aimed at ensuring the explainability of AI and is implemented in three areas: organizational (access to information, ensuring participation in the decision-making process), technical (access to the source code of the system) and content (completeness, reliability and availability of information about the algorithm). The principle can be improved by introducing into algorithms the function of generating reports with a variation of content depending on the qualification of the requestor, as well as providing information about the current indicators of metrics.

The question of AI's legal capacity is highly debatable. The solution of this problem mainly depends on the technology's controllability by a human being: control over the algorithm's operation does not naturally lead to the emergence of any subjectivity in AI. The analysis of the doctrine has shown that from the point of view of the theory of law there are no obstacles to recognizing as a subject of law AI-systems that can possess legal will (expressed through the ability to autonomous thinking activity) and can be autonomous, i.e. make final decisions without human control.

Critics of this approach adhere to an anthropocentric approach in the understanding of law, distorting the legal nature of AI, which they seek to liken to a human being. The most appropriate concept, in our opinion, is to recognize AI (taking into account socio-economic, cultural and political factors of a particular national legal order) as a subject of a special kind (sui generis), since algorithms (1) can possess legal will and (2) make final decisions without human intervention. At the same time, the scope of legal personality of AI systems should be dynamic, i.e. it should depend on the field of their application and the level of technological development. In the field of medicine, the recognition of such a truncated legal personality of AI will make it possible to organize a fully autonomous process of medical care without human participation. At the same time, taking into account the current level of technological development, the existing medical AI systems require increased human control. At present, the question of AI legal personality is premature, and the existing medical algorithms are objects of rights: computer programs and medical devices.

We have repeatedly emphasized, based on the analysis of international law sources and legal doctrine, that the main purpose of legal regulation of intellectual technologies is to ensure the safety of their use. In turn, the safety of AI use in medicine, in our opinion, is achieved through (1) proper implementation of the procedure for obtaining informed voluntary consent to medical intervention and processing of personal data, (2) creation of a system of quality control of algorithms within the regime of

medical devices circulation, and (3) fixing an effective mechanism of tort liability for harm caused by the intellectual system.

The procedure for obtaining informed voluntary consent for medical intervention (including participation of a person in biomedical research) should be adapted to the conditions of digitalization of health care. The technical complexity of algorithms and the non-transparency of their decision-making mechanism give rise to problems of the appropriate format, accessibility and volume of information about the medical intervention that should be communicated to the patient. Analysis of the applicable legal regulation has shown that these issues are currently unresolved, and in general – there is no obligation to inform the patient about the use of intelligent systems in the process of the proposed intervention itself.

Given the direct relationship between obtaining informed voluntary consent and the patient's state of health, observance of his/her rights and legitimate interests, a special unified procedure for obtaining consent should be enshrined in an international legal act for cases of AI interventions. The relevant legal act should include provisions on: (1) ensuring transparency of the algorithm's decision-making process, including the obligation to provide up-to-date metrics; (2) providing full information on the purpose, consequences of the intervention, and the probability of complications depending on the method of intervention (with or without the use of AI); (3) informing the patient about the results of diagnosis and previous treatment. At the moment, the most obvious measure that requires legal regulation is obtaining informed consent for the use of algorithms when performing a particular medical intervention.

International legal regulation in terms of exceptions to the general rule on the need to obtain informed voluntary consent for medical intervention is well developed and does not require changes in connection with the use of AI. However, it is quite obvious that sooner or later in the sphere of legal regulation of the use of AI we will sooner or later have to face competition between personal and public interests. In our opinion, the interests of public safety will prevail here, provided that the criteria of admissibility of interference in human rights and freedoms, which are enshrined in Sec. 2 of Art. 29 of the Universal Declaration of Human Rights of 1948 (and Art. 26 of the Oviedo Convention of 1997 – in relation to interference in the sphere of human health protection), are met.

Another area of AI security is the protection of confidentiality of personal data, a type of which is health data. The problem of the «black box» (i.e. the unexplainability of the process of obtaining results and decisions reached by the algorithm) makes it difficult to implement the procedure for obtaining informed voluntary consent to the processing of personal data. The very nature of AI-technologies, which require a large amount of information to create and operate, contradicts the principles of data minimization and purposefulness of data processing.

A universal international legal instrument enshrining obligations in the field of personal data protection has yet to be developed. This work will be quite complex, given the technological gap between

developed and developing countries. Particular care should be taken when using the currently available developments, including those of institutions such as the EU and the Council of Europe. The focus on extreme individualism and formalism within these institutions cannot be supported in the development of universal regulators. At the same time, the set of requirements for personal data protection and ensuring the security of their automated processing is of certain interest. Nevertheless, the regional and ideological specificity of the legal framework of these actors should be taken into account, as it requires significant adjustment, including taking into account the experience of the Russian Federation. Thus, the legal regulation within the European institutions is based on an unjustified priority of life and health protection over the confidentiality of personal data, as well as contains restrictions on the right of the subject to exercise control over his/her personal data. In this regard, it is necessary to clarify the condition of personal data processing without the subject's consent by including an additional condition on the objective impossibility of obtaining the subject's consent or the exclusion of such exceptions to the collection of personal data.

At the same time, the effectiveness of the existing regulation currently depends more on the practice of its application and the dissemination of better software measures to detect and suppress threats to the processing of personal data. The envisaged legislative and organizational-technical measures are sufficient and can ensure the protection of personal data to the extent that the security of such data does not depend on technological rivalry, methods of unauthorized access and protection of information systems.

Quality control of intelligent systems for medical use is carried out within the framework of a special regime of medical devices circulation, which includes such administrative procedures as passing technical and clinical tests, state registration of medical devices, requirements to the content of technical and operational documentation, as well as special rules of production, circulation, storage, transportation, adjustment, operation, maintenance and disposal of medical devices. Passage of the above procedures and compliance with the requirements ensures the admission of safe algorithms for use in medical practice.

At the same time, despite its key importance for ensuring the safety of intellectual developments, the circulation regime of medical devices using AI is currently practically not subject to international legal regulation. The national standards of GOST R 59921.*-2021 series dedicated exclusively to the peculiarities of medical AI systems circulation may serve as a basis for future international agreements and decisions of international organizations in the field of control over the circulation of medical devices. Despite the need for further improvement of the procedures set forth in these documents, the content of these national standards covers the key stages of development of AI systems.

One of the main features of AI – its learnability – remains unattended by the legislator, due to which an algorithm can change its performance indicators during its life cycle and become unsafe

without proper control and maintenance after its registration as a medical device. In this regard, the special legal regime for medical devices could be improved by introducing a mechanism for assessing the performance parameters (using a set of metrics, including ROC AUC) and maintenance of AI systems at the post-registration stage throughout their life cycle. In order to ensure safety, the principle of protection by design should also be enshrined, the essence of which is to build into the algorithm program measures and constraints aimed at preventing harm. An integral part of this concept are the requirements for ensuring the protection of AI itself.

Special attention should be paid to the requirements for AI training: this stage of algorithm development currently remains outside the legal regulation. Based on the analysis of scientific literature, we have formed a number of rules (data from each dataset component should be mutually representative, it is necessary to provide several independent tests based on datasets from different compilers, etc.), but this area of legal regulation should be studied separately. The importance of legal regulation of this stage of AI development is evidenced by the growing attention of non-governmental international organizations (e.g., WMA) to the training of algorithms.

Addressing the problem of liability for damage caused by AI, we came to the conclusion that the traditional compositions of special torts (causing harm by a source of increased danger or due to defects of goods) do not take into account the specifics of technology (its autonomy) and cannot be applied in the field of medicine. In healthcare as an area of high social significance, where the price of an error is the life and health of a person, the professional participants must inevitably be subject to stricter standards of responsibility, including the principle of personal responsibility of a doctor for the consequences of decisions made in an automated order. This approach is relevant nowadays, when AI is not isolated and is under human control.

A special corpus delicti liability for harm caused by medical AI should be based on the combination of the general tort and risk management principles in cases where the fault of a particular person cannot be established or such harm is not unlawful. The basis for liability should be considered the infliction of harm as a result of the failure of a participant in an AI relationship to comply with the procedures required as part of control over the circulation of medical devices, including the rules for the development, production, transportation, storage, sale, operation, maintenance and decommissioning of AI systems, which are set out in regulations, technical and operational documentation or are assumed as part of good faith behavior. In turn, a physician is held liable based on the principle of risk management when the following conditions are simultaneously met: (1) the rules within the medical device regime have not been violated; (2) the harm causer and the victim acted in good faith; (3) the harm causer assumed the risk of harm within the framework of the professional presumption, and (4) the victim did not accept the risk of harm within the framework of the procedure of providing informed voluntary consent for medical intervention.

International cooperation, being a principle of both international law in general and international medical law and international legal regulation of the achievements of STP – in particular, plays a crucial role in regulating the use of AI in the field of medicine and ensuring its safety. There is a tendency to formalize relations in the AI-sphere through more detailed regulation of the legal regime of intellectual technologies. The main goal of international cooperation in AI should be to minimize the risks of harm to humans and states, which may result from uncontrolled development of dual-use technologies with unconditional guarantees to ensure the national security of states, which is especially important for the Russian Federation in the current geopolitical situation.

Ensuring the safety of AI is achieved through the harmonization of information exchange processes and data format, the establishment of common principles for the admission of intellectual systems into civil circulation, as well as the development of an effective liability mechanism. In this regard, the development and improvement of the system of technical standards in general is one of the most priority areas of cooperation and international legal regulation of modern technologies. Thus, unification of technical and clinical testing procedures will allow to ensure a single safety standard within the framework of an interstate organization or integration association (which is the most likely). Bringing to uniformity technical regulations (primarily in the field of creation, operation and maintenance of algorithms), in turn, will ensure the compatibility of intellectual systems and information networks of states.

Unification of information exchange processes, scaling of databases and interoperability of information networks at local, regional and national levels is one of the main objectives of international cooperation in the field of health care. Standardization of data format, cataloguing and storage, introduction of publicly available systems for searching, indexing and quality checking of datasets, and overcoming copyright restrictions are key. The already existing and actively used in medical practice protocols DICOM, HL7, IHE profiles can be taken as a basis for international standards in this area. Attention should also be paid to the development of communication infrastructure. In turn, one should be cautious about the current trend of data localization through the establishment of national restrictions for their cross-border movement, as well as subordination of data collection, processing and storage procedures to one jurisdiction.

International cooperation in the field of intellectual property is no less important. Labor-intensive creation of predictive models of algorithms and formation of databases determines the need to establish a balance between the protection of the economic interest of the right holder and the interests of society (ensuring health, STP and competition). To achieve this goal, the establishment of national treatment and most-favored-nation treatment in the field of intellectual property, as reflected in Art. 3 and 4 of the TRIPS Agreement of 1994, will help. To promote cooperation in the field of AI and the creation of venture capital enterprises with foreign participation, states should improve the institution of joint

ownership of intellectual property and take measures to reduce administrative barriers to ensure their protection.

Developments in AI will be facilitated by improving technical means of protecting intellectual property rights and expanding the use of so-called inclusive regulatory mechanisms, such as Creative Commons licenses, free software and alternative compensation, compulsory licensing, and public domain regimes. A positive trend is to encourage the creation of digital platforms to host datasets under common terms of use (such as Kaggle, Papers with Code, Google Dataset Search, etc.).

It is also of great importance to harmonize the positions of states on the issue of limitation of intellectual property rights, the condition of which should be the pursuit of a legitimate aim (to ensure vital public interests) and the provision of remedies to right holders against abuses. Bringing such restrictions to uniformity will provide legal certainty in the regulation of relations related to the creation and exchange of AI technologies. At the same time, there is a lack of provisions facilitating the free use of developments for scientific purposes, which necessitates the regulation of such an exception in the sources of international law.

In the field of AI, the technical and financial cooperation of states comes to the fore, without which the creation of safe algorithms will be extremely difficult. The implementation of the principles of international medical law and the framework for regulating STP involves strengthening international cooperation between developed and developing States in order to reduce the technological gap between them, increase the coverage of the population with health services and improve their quality. In order to bridge the scientific and technological gap and increase the delivery of high-technology health care, states should share law enforcement experience, establish preferential legal treatment for innovative developments in developing countries, and improve digital literacy and promote the development of information and communications technology infrastructure.

The need for legal regulation of relations related to the use of AI in medicine, pharmacology and biology raises the question of the sources of international law that best correspond to the specifics of the subject of regulation. The high dynamics of social relations caused by STP determines the need to choose international legal instruments that provide both flexibility and stability of legal regulation. In our opinion, the adoption in the near future of an international legal act containing formally defined and enforceable obligations of states in the field of AI use is unlikely, since each state has its own level of financial, organizational, technical and personnel support of the national health care system. The creation of an international model law, declaration and international standards seems most likely. Despite the non-binding nature of the norms contained in these acts, their incorporation within the framework of integration associations and national legal orders is inevitable.

In addition to the enshrinement of norms in the sources of international law, the implementation of international legal norms in the field of AI requires an effective mechanism to monitor compliance.

Relations related to the use of AI are currently considered by a multitude of sovereign and non-sovereign actors with different competencies, which inevitably raises the issue of coordination of existing rule-making, which is currently lacking. At present, there is a real risk of haphazard development of a contradictory set of norms in the field of AI without forming a coherent system, as evidenced by the current state of legal regulation of intellectual technologies.

Thus, the regulation of certain aspects of the use of AI (including in medicine) is carried out in international interstate (WHO, UNESCO, ITU, WIPO, WTO) and non-state organizations (WMA, CIOMS, ISO, IMDRF), by a special commission within the framework of the integration entity (EU), as well as by many individual states (Russia, USA, UK, China, Canada, Israel, Kingdom of Saudi Arabia, etc.) and non-governmental organizations (NEMA, IEEE, etc.). For this reason, today it is relevant not to establish a new specialized international organization or to expand the competence of existing associations, but to create an international body to coordinate normative and law enforcement activities in the field of using AI technologies. In our opinion, it is advisable to create a special body within the UN (in accordance with Sec. 2 Art. 7 and 22 of the UN Charter), similar to the UN Commission on International Trade Law, which would be entrusted with the function of coordinating on a non-discriminatory basis international legal, integration and domestic regulation of the use of II technologies.

The implementation by the Russian Federation of the principal normative provisions and conclusions set forth in this dissertation research for the development of a unified international legal framework for cooperation in the field of AI will strengthen Russia's position in the international arena as an influential world power, making a decisive contribution to maintaining global security and ensuring the peaceful development of states, and open wide opportunities for successful activity of the Russian Federation in the international arena as one of the responsible, influential and independent centers of the modern world, which is one of the main national interests of Russia in the foreign policy sphere (paragraphs 14 and 16 of the Concept of Foreign Policy of the Russian Federation).

We hope that this dissertation research will improve the legal regime for the use of intellectual technologies, which is enshrined in the current sources of international, integration and national law, as well as help in solving problems in the field of medicine, caused by the emergence of artificial intelligence – the prototype of a new participant in social relations, which can significantly improve the quality, timeliness and accessibility of health care services, as well as improving the state of national health care systems and strengthening constructive interstate cooperation in the field of health protection for the benefit of both the Russian Federation and its citizens, as well as the whole of humanity[444].

[444] Progressive development of mankind is part of the Concept of Foreign Policy of the Russian Federation (see paragraphs 5, 22, 47 of the document).

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Appendix A

APPLICATION OF ARTIFICIAL INTELLIGENCE IN MEDICAL PRACTICE

The use of AI in medicine is viewed positively by many researchers[445] due to the unique capabilities of the technology. AI allows detecting hidden abnormalities, pathologies and patterns by analyzing large volumes of heterogeneous data[446], which humans cannot process in a short period of time. AI is effective for diagnostics, creation of new drugs and treatment of orphan diseases, which are characterized by low diagnosability and a small number of patients[447].

Algorithms are able to process and systematize complex data on health status, medical history and treatment methods in a volume exceeding the productivity of a single doctor[448], which contributes to a more accurate determination of the causes and conditions of disease (etiology)[449], provides an individual approach to each patient, and makes it possible to continuously monitor the state of health[450]. An example is the MySurgeryRisk AI system, which, based on the analysis of available medical information about a patient and guided by 285 variables, is able to determine the risk of postoperative complications, as well as provide a forecast of mortality at 1, 3, 6, 12 and 24 months[451] with greater accuracy than experts[452].

Intelligent systems are also capable of determining the risks of certain therapies[453], the effectiveness of a drug (Oncobox project[454]) or the most effective methodology at all (precision medicine)[455],

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which naturally frees up the doctor's time, which he can allocate to atypical tasks[456] and help more patients[457]. Using AI algorithms in their work, doctors can automate routine processes and make more informed decisions, reducing the probability of medical error[458] by an average of 70%[459].

Intelligent technology can help patients better understand the meaning and implications of clinical decisions[460] and reduce health care costs[461]. Cost optimization is industry-wide: in the U.S., the use of big data techniques can reduce healthcare costs by up to 17% of annual expenditures[462].

AI helps to solve the global problem of the shortage of medical personnel in the national health care system[463]. In the Russian Federation, an average of 1 specialist per 3,000 people is engaged in diagnostics, in the United States – 1 specialist per 10,000 people, while in Bangladesh diagnostics is performed by 1 doctor per 1 million people[464]. As of 2019, to keep up with demand, a radiologist must, on average, process one radiograph, fluorogram, or CT/MRI image every 3-4 seconds for a full workday[465]. Due to increasing volumes of data, much of it remains unstructured and unutilized. The use of AI makes it possible to process and systematize such data in a relatively short period of time[466].

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[460] Erivantseva T.N. Op. cit. P. 271.

[461] An introduction and overview of machine learning in neurosurgical care / J.T. Senders [et al.] // Acta Neurochirurgica. 2018. Vol. 160. № 1. P. 29-38.

[462] Groves P. The «big data» revolution in healthcare: Accelerating value and innovation [Electronic resource] / P. Groves [et al.]; McKinsey & Company. [New-York], 2016. URL: http://repositorio.colciencias.gov.co/bitstream/handle/11146/465/1661-The_big_data_revolution_in_healthcare.pdf?sequence=1&isAllowed=y (date of access: 30.05.2023).

[463] Artificial Intelligence in Radiology: A Call for Thoughtful Application [Electronic resource] / C.N. Driver [et al.] // Clinical and translational science. 2020. Vol. 13. № 2. P. 216–218. doi: 10.1111/cts.12704; Modern technologies of medical image evaluation in the era of digitalization / I.A. Baranov [et al] // Scientific and Medical Bulletin of the Central Black Earth Region. 2021. № 83. P. 15; Tyurin I.E. Radiation diagnostics in the Russian Federation in 2014 / I.E. Tyurin // Bulletin of Radiology and Radiology. 2015. № 6. P. 56-63; Shelekhov P.V. Efficiency of radial diagnostics equipment utilization in the subjects of the Russian Federation / P.V. Shelekhov // Health Care Manager. 2017. № 5. P. 33-41; Shchepin V.O. On the issue of staffing of radiology diagnostic units / V.O. Shchepin // Problems of social hygiene, public health and history of medicine. 2014. Vol. 22. № 5. P. 42-45.

[464] Suvorova N. Specialist in radiation diagnostics Sergey Morozov: artificial intelligence will take over 30% of the functions of a doctor and up to 60% of the functions of laboratory technicians [Electronic resource] // HIGHTECH.FM: media portal about technologies «Hitech». 2018. May 31. URL: https://m.hightech.fm/2018/05/31/AI-for-medicine (date of access: 30.05.2023).

[465] Driver C.N. Op. cit.

[466] Prospects and challenges for clinical decision support in the era of big data [Electronic resource] / I. El Naqa [et al.] // JCO Clinical Cancer Informatics. 2018. Vol. 2. doi: 10.1200/cci.18.00002; Translating cancer genomics into precision medicine with artificial intelligence: applications, challenges and future perspectives / J. Xu [et al.] // Journal of Human Genetics. 2019. Vol. 138. № 2. P. 109-124; IBM and health care – how Watson helps people [Electronic resource] //

The increase in workload is directly proportional to the probability of making medical errors. The solution to this problem may be the introduction of AI[467], which does not «get tired» and always gives the same result without loss of speed[468]. The AI solution can act as a «third opinion» in case of contradiction of opinions of several specialists[469], which will increase the overall accuracy of clinical decisions. For example, in radiology, back in 2016, the use of AI improved the accuracy of diagnoses by an average of 30-40%[470].

Algorithms are particularly effective in processing visual information[471]: image modeling, restoration of missed areas of the image during examination[472], and generally contribute to the improvement of medical image processing techniques[473]. The use of AI in CT image processing provides noise reduction while maintaining image quality[474], and in the field of oncology, the algorithm is able to recognize skin malignancies from photographs with the accuracy of dermatologists[475].

Medical AI systems are currently used in the following main areas: diagnostics[476], health monitoring and patient care, medical drug research (pharmacology), document optimization, calculation of risks of disease progression, the use of therapy or other clinical decisions[477], and patient triage[478]. Diagnostics is the most popular area of medical application for AI algorithms, which is achieved due to the large amount of accumulated diagnostic information (in particular, the results of radiation diagnostics).

MARKETING.MEDSTEG.RU: the site of the company «Medsteg». [2020]. URL: https://marketing.medsteg.ru/healthcare-marketing/2017/11/ibm-watsonhtml (date of access: 30.05.2023).

[467] Blokhin I.A. Op. cit. P. 275.

[468] Lukyanchenko V.V. Op. cit. P. 87; Borisov D.N. Op. cit. P. 27.

[469] Lakhani P. Deep learning at chest radiography: Automated classification of pulmonary tuberculosis by using convolutional neural networks / P. Lakhani, B. Sundaram // Radiology. 2017. Vol. 284. P. 574-582.

[470] El Naqa I. Op. cit.

[471] Pesapane F. Artificial intelligence in medical imaging: threat or opportunity? Radiologists again at the forefront of innovation in medicine [Electronic resource] / F. Pesapane, M. Codari, F. Sardanelli // European radiology experimental. 2018. Vol. 2. № 1. doi: 10.1186/s41747-018-0061-6.

[472] Machine learning to predict the long-term risk of myocardial infarction and cardiac death based on clinical risk, coronary calcium, and epicardial adipose tissue: a prospective study / F. Commandeur [et al.] // Cardiovascular Research. 2020. Vol. 116. № 14. P. 2216-2225.

[473] Oikonomou E.K. Artificial intelligence in medical imaging: a radiomic guide to precision phenotyping of cardiovascular disease / E.K. Oikonomou, M. Siddique, C. Antoniades // Cardiovascular Research. 2020. Vol. 116. № 13. P. 2040-2054.

[474] Artificial intelligence in cardiovascular imaging: state of the art and implications for the imaging cardiologist / K.R. Siegersma [et al.] // Netherlands Heart Journal. 2019. Vol. 27. № 9. P. 403-413.

[475] Esteva A. Op. cit.

[476] Gusev A. Artificial intelligence for health and healthcare: a report of researchers from the United States [Electronic resource] // WEBIOMED.AI: official website of the system of predictive analytics and patient risk management «Webiomed». 2018. 7 April. URL: https://webiomed.ai/blog/iskusstvennyi-intellekt-dlia-zdorovia-i-zdravookhraneniia-otchet-issledovatelei-iz-ssha/ (date of access: 30.05.2023).

[477] Ivanova A.P. Legal problems of using artificial intelligence in health care / A.P. Ivanova // Social and Humanities. Domestic and foreign literature. Series 4: State and Law. Abstract journal. 2021. № 1. P. 152; Chernykh E.E. Main directions of strategies for the development of artificial intelligence in medicine. P. 75.

[478] Blokhin I.A. Op. cit. P. 276; Vardhanabhuti V. CT scan AI-aided triage for patients with COVID-19 in China [Electronic resource] / V. Vardhanabhuti // Lancet Digit Health. 2020. Vol. 2. № 10. P. e494–e495. doi: 10.1016/S2589-7500(20)30222-3.

In the field of clinical image processing, a stable system of deep learning methods has already been established[479].

These capabilities of intelligent algorithms allow them to be actively used as medical decision support systems (MDSS)[480], which contribute to the correct and most effective decision-making by a specialist[481]. The complex application of AI-based MDSS can: enhance the effectiveness of treatment, making it more individualized[482]; ensure high adherence to therapy[483]; prevent the development of complications and, consequently, reduce mortality[484], and optimize the material, technical and human resources of a medical organization[485] by prioritizing patients with a higher chance of hospitalization[486].

AI is also being used in the increasingly popular field of telemedicine, which encompasses a set of methods of remote delivery of medical care (the «doctor-patient» model) and remote interactions between medical professionals (the «doctor-doctor» model)[487]. AI-technologies make it possible to perform primary diagnostics and help the «online» doctor in making further clinical decisions, which will also reduce the workload of, first of all, therapists[488].

Thus, medical AI is now being used as a tool[489], that reduces the workload of medical staff by handling a number of routine tasks and processes[490], as well as assisting specialists in making medical decisions, leaving the final say to the human[491].

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[479] Meldo A.A. Artificial intelligence in medicine: current state and main directions of development of intellectual diagnostics / A.A. Meldo, L.V. Utkin, T.N. Trofimova // Radiation Diagnostics and Therapy. 2020. Vol. 11. № 1. P. 11.

[480] Gavrilov D.V. Algorithm of suspicion formation for a new coronavirus infection based on the analysis of symptoms for use in the support system of medical decision-making / D.V. Gavrilov, A.V. Kirilkina, L.V. Serova // Physician and Information Technologies. 2020. № 4. P. 52.

[481] Support system for medical decision making / O.Y. At'kov [et al.] // Physician and Information Technologies. 2013. № 6. P. 67-68.

[482] Cosgriff C.V. Critical care, critical data [Electronic resource] / C.V. Cosgriff, L.A. Celi, D.J. Stone // Biomedical Engineering and Computational Biology. 2019. Vol. 10. doi: 10.1177/1179597219856564.

[483] Adherence to long-term therapies, evidence for action [Electronic resource] / World Health Organisation. Geneva, 2003. URL: https://www.who.int/chp/knowledge/publications/adherence_full_report.pdf (date of access: 30.05.2023).

[484] Intensive care unit telemedicine in the era of big data, artificial intelligence, and computer clinical decision support systems / R.D. Kindle [et al.] // Critical Care Clinics. 2019. Vol. 35. № 3. P. 483-495.

[485] El Naqa I. Op. cit.; Xu J. Op. cit.

[486] Clinical decision support systems for triage in the emergency department using intelligent systems: a review [Electronic resource] / M. Fernandes [et al.] // Artificial Intelligence in Medicine. 2020. Vol. 102. doi: 10.1016/j.artmed.2019.101762.

[487] Kleimenova L. What is telemedicine? [Electronic resource] // TRENDS.RBC.RU: network edition «RBC Trends». 2021. 23 July. URL: https://trends.rbc.ru/trends/innovation/5d8e297f9a79478c40cd4369 (date of access: 30.05.2023).

[488] Varyushin M.S. Legal regime of artificial intelligence technologies used in telemedicine / M.S. Varyushin // Russian Journal of Telemedicine and Electronic Health Care. 2021. № 7 (2). P. 19.

[489] Implementing Machine Learning in Radiology Practice and Research / M. Kohli [et al.] // American Journal of Roentgenology. 2017. Vol. 208. № 4. P. 754-760.

[490] Ivshin A.A. Op. cit. P. 141.

[491] Chernykh E.E. Digital medicine: risks of legal implementation of innovations in the field of health care. P. 90.

Appendix B

CHALLENGES OF IMPLEMENTING MEDICAL AI

Modernization of healthcare through the introduction and application of AI technologies entails both positive changes and the emergence of no less significant problems. Mere automation of processes and haphazard innovation without structural transformation of the industry will not lead to real progress and economic development[492]. As noted in a Deloitte study based on a survey of experts from the North American and European regions, only 40% of respondents consider the spread of AI systems and robotics as an independent factor of development, while 88% of experts gave fundamental importance to the organizational principles of the new economic structure, which is based on AI[493]. The introduction of AI naturally leads to the emergence of new or aggravation of existing socio-economic, ethical, legal and other problems, among which we can highlight the following:

Unemployment. The use of new technologies will inevitably lead to a change in the role of medical personnel. This circumstance is considered in the literature from two perspectives: (1) AI systems will replace humans, which will lead to increased unemployment, and (2) the introduction of technology will cause a global retraining of medical personnel[494] and the emergence of new specialties, otherwise, the person will not be able to integrate into the realities of the new labor market and will also face unemployment[495].

The process of transformation of the labor market is observed at the introduction of technological innovations at any stage of the industrial revolution, in this regard, the above problem invariably accompanies progress and implementation of its results in various spheres of the economy. The problematic point lies not so much in the loss of demand for certain professions as in the scale of this process. According to some experts, AI is capable of replacing up to 80% of existing medical specialties due to greater efficiency, accuracy of diagnoses and economic benefits[496]. Due to the success of AI in the field of visual data processing, one of the founders of the deep learning method – J. Hinton – In 2016 declared that there is no need for radiologists at all[497].

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[492] Kolesnichenko O.Y. Op. cit. P. 25.

[493] Rewriting the rules for the digital age [Electronic resource]: 2017 Deloitte Global Human Capital Trends: report / Deloitte. London: University Press, 2017. 137 p. URL: https://www2.deloitte.com/content/dam/Deloitte/uy/Documents/human-capital/Human-capital-trends_2017.pdf (date of access: 30.05.2023).

[494] Lukyanchenko V.V. Op. cit. P. 85.

[495] Chernykh E.E. Digital medicine: risks of enforcement of innovations in health care. P. 88.

[496] Clark L. Vinod Khosla: Machines will replace 80 percent of doctors [Electronic resource] // WIRED.CO.UK: a technology news portal «Wired». 2012. 4 September. URL: http://www.wired.co.uk/article/doctors-replaced-with-machines (date of access: 30.05.2023).

[497] AI, radiology and the future of work [Electronic resource] // ECONOMIST.COM: a news portal «The Economist» dedicated to global politics, business and economics. 2018. 7 June. URL: https://www.economist.com/leaders/2018/06/07/ai-radiology-and-the-future-of-work (date of access: 30.05.2023).

Awareness of insufficient qualifications, coupled with the psychological state of expectation of impending redundancy, leads to the risk of the phenomenon of «shifting blame» to the AI for medical errors, as well as an increase in internal conflicts[498]. In such a situation, it is particularly important for the legislator, in order to reduce the risk of social tension, to develop support measures for people who have lost their jobs, in the form of retraining, assistance in finding a job functionally close to the previously performed job duties, as well as the payment of temporary benefits.

Degradation of professional skills. Some researchers note that the introduction of AI in the field of medicine and the automation of some medical functions will lead to the loss of skills of specialists in the relevant fields (radiation diagnostics, diabetes treatment, etc.)[499]. It is feared that doctors will stop recognizing symptoms of diseases, signs of pathology or, for example, describing radiographs, relying entirely on AI, resulting in weaker quality control of algorithms[500].

Professional burnout. Specialists note that the automation of more and more processes in medicine will lead to the realization by medical and medical workers of the uselessness of their knowledge and devaluation of their work function, which will lead to a decrease in the quality of services and professional burnout[501].

Lack of databases. Developers will face a shortage of large and high-quality databases for AI training[502], and it is impossible to collect sufficient data for a number of clinical trials[503]. The problem is aggravated by the lack of uniform standards for the form and structure of medical data, as well as the results of their markup, which complicates the development and use of safe algorithms.

Lack of a full-fledged legal regime for AI. Difficulties in the regulation of AI are found at the fundamental level: there is no universal definition of AI and the concept of tort liability. Due to the lack of a clear understanding of the nature of intellectual technologies, the very object of legal regulation is blurred, which leads to gaps, conflicts and errors in legal technique[504].

Mistrust in AI. The unexplained results of algorithms have a negative impact on trust in AI, its spread and application possibilities, both on the part of patients who are not ready psychologically to entrust their life and health to an algorithm, and on the part of specialists, among whom there is a strong adherence to the traditional approach in medicine[505]. The more serious consequences of such «neo-

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[498] Chernykh E.E. Digital medicine: risks of enforcement of innovations in health care. P. 89.

[499] Ivanova A.P. Op. cit. P. 157.

[500] The ethical, legal and social implications of using artificial intelligence systems in breast cancer care / M.S. Carter [et al.] // The Breast. 2020. Vol. 49. P. 29-30.

[501] Fomina N.V. Labor satisfaction as a factor of professional success of a doctor / N.V. Fomina, I.V. Lebedeva // Problems of modern pedagogical education. 2016. № 53-11. P. 260-267.

[502] Borisov D.N. Op. cit. P. 30; Meldo A.A. Op. cit. P. 11.

[503] Ivshin A.A. Op. cit. P. 136.

[504] Lukyanchenko V.V. Op. cit. P. 86.

[505] Char D.S. Implementing Machine Learning in Health Care – Addressing Ethical Challenges / D.S. Char, N.H. Shah, D. Magnus // New England Journal of Medicine. 2018. № 378 (11). P. 981-983.

Luddism» are an increasing burden on doctors, a decrease in the quality of medical services and technological stagnation[506].

Algorithmic bias. AI bias is caused by the ability of algorithms to find relationships invisible to humans based on the analysis of large amounts of data[507]. Experts note that AI can establish a cause-and-effect relationship between two unrelated factors based solely on statistical analysis[508]. In the field of medicine, an algorithm can determine the predisposition or risk of a certain disease solely on the basis of a person's ethnicity, gender, race or other patterns that clearly cannot act as an objective cause[509], thus creating a threat of discrimination[510].

Vulnerability of AI to hacking. Since AI is software, there is a risk of unauthorized interference in its operation. Hacking of the algorithm may lead to damage to property, life and health, violation of medical confidentiality, leakage of personal data, as well as other violations of human rights and freedoms.

Lack of standardization. Attention should be paid to the lack of universally recognized standards in terms of clinical trials, evaluation of effectiveness and stability of medical AI[511]. There is also a lack of a full-fledged set of procedures to control the development, distribution and use of AI[512], the rules for certain activities using AI are not regulated, which may lead to the entry of low-quality systems into the market, as well as in general – to create a risk of uncontrolled development of technologies, which prompts some experts to speak in favor of a moratorium on the creation of new versions of «strong» AI until the development of a full-fledged legal regulation of intellectual technologies[513].

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[506] Chernykh E.E. Digital medicine: risks of enforcement of innovations in health care. P. 88.

[507] Antoniades Ch. Op. cit. P. 122.

[508] Ivanova A.P., Op. cit. P. 158; Antoniades Ch. Op. cit. P. 117.

[509] Davenport T. The potential for artificial intelligence in healthcare / T. Davenport, R. Kalakota // Future Healthcare Journal. 2019. Vol. 6. № 2. P. 97.

[510] Zueva A.I. Balance of interests of artificial intelligence and human capital in the digital economy: challenges and threats to sustainable development of business and economy // Economy and society: modern models of development. Vol. 11. № 1. P. 78.

[511] Borisov D.N. Op. cit. P. 30.

[512] Chernykh E.E. Digital medicine: risks of legal implementation of innovations in the field of health care. P. 87.

[513] See Pause Giant AI Experiments: An Open Letter [Electronic resource]: Open Letter // FUTUREOFLIFE.ORG: official website of Future of Life Institute. [Cambridge], 2023. URL: https://futureoflife.org/open-letter/pause-giant-ai-experiments/ (date of access: 30.05.2023).

Appendix C

CONCEPT OF ARTIFICIAL INTELLIGENCE

The legal regime of artificial intelligence should be based on a clear understanding of what the technology is, what its legal properties and specificity are. The answer to this question determines the model and content of legal regulation, its main sources and principles[514]. The existing body of normative-legal acts does not contain a unified definition of the concept of artificial intelligence[515]. This significantly complicates the development of consistent and holistic regulation due to the lack of understanding of its object and lack of systematization of the categorical apparatus[516].

When analyzing the definitions of AI, which are given by legal scholars, we risk getting confused in the jumble of numerous features and properties, which are seen as an object of legal regulation for artificial intelligence. Below are the results of the analysis of a number of definitions that are found in the domestic scientific literature:

Criterion	**AI feature**	**Author**
Form of existence	Computer hardware and software	Morhat P.M.[517], Ponkin I.V., Redkina A.I.[518]
	Virtual	Morhat P.M.
	Cyberphysical	
	Cybernetic	Morhat P.M., Ponkin I.V., Redkina A.I.
	Electromechanical	Ponkin I.V., Redkina A.I.
	Bio-electronic-mechanical	
	Hybrid	
Structural elements	Cognitive-functional architecture	Ponkin I.V., Redkina A.I.
	Computing capacities of the required capacity and speed	
	Presence of a technical device (cyber-physical system) to perceive information and transmit it	Vasiliev A.A., Shpoper D.[519], Morhat P.M.

[514] Ponkin I.V. Artificial intelligence from the point of view of law / I.V. Ponkin, A.I. Redkina // Bulletin of Peoples' Friendship University of Russia. 2018. № 1. P. 98.

[515] Vasiliev A.A. Artificial intelligence: legal aspects / A.A. Vasiliev, D. Shpoper // Izvestiya AltSU. Legal sciences. 2018. № 6 (104). P. 24; Morhat P.M. Legal personality of artificial intelligence in the field of intellectual property law: civil-law problems: dissertation. ... doctor of jurisprudence. sciences / P.M. Morhat. M., 2018. P. 73; Laptev V.A. Op. cit. P. 82.

[516] Baranov P.P. Legal regulation of robotics and artificial intelligence in Russia: some approaches to solving the problem / P.P. Baranov // North Caucasus Legal Bulletin. 2018. № 1. P. 41.

[517] Morhat P.M. Artificial intelligence: a legal view / P.M. Morhat. Moscow: Buki Vedi, 2017. P. 43-69.

[518] Ponkin I.V. Artificial intelligence from the point of view of law. P. 94-95.

[519] Vasilyev A.A. Op. cit. P. 26.

	Complex machine-biological algorithmic complex of processes	Zaplatina T.S.[520]
A form of life	Lack of life	Morhat P.M., Vasiliev A.A., Spoper D.
	Artificial system	Ponkin I.V., Redkina A.I.
System capabilities	Anthropomorphic-intelligent thinking and cognitive actions	Kurzweil P.[521], Morhat P.M., Borisov D.N., Kushnirchuk I.I., Sevryukov V.V., Kovalenko E.I.[522]
	Ability to analyze, build logical chains, generalize (including large amounts) of information, develop intellectual solutions based on the studied data (thinking), self-awareness.	Vasiliev A.A., Shpoper D.; Meldo A.A., Utkin L.V., Trofimova T.N..[523]; Eidenmueller H.[524], Zueva A.I.[525]
	Substantive performance of certain anthropomorphic-emulating cognitive (including cognitive-analytical and creative, as well as self-awareness and learning) functions. High-level ability to perceive and model surrounding images and symbols	Ponkin I.V., Redkina A.I.
	Self-referral, self-regulation, self-adaptation, self-restraint	Morhat P.M.
	Independent modeling and correcting algorithms of actions for oneself	Ponkin I.V., Redkina A.I.
	Self-maintenance of self in homeostasis	Morhat P.M.
	Genetic search (search with preservation of elements of «parental information» for further processing), recording, accumulation and reproduction (emulation) of experience and information	Morhat P.M., Ponkin I.V., Redkina A.I.
	Learning and self-learning from one's own experience, «self-homologation»	Morhat P.M.; Malyshkin A.V.[526]; Vasiliev A.A., Shpoper D.; Borisov D.N., Kushnirchuk I.I., Sevryukov V.V., Kovalenko E.I.; Zueva A.I.

[520] Zaplatina T.S. Legal approaches to the regulation of artificial intelligence and robots in the European Union and its member states / T.S. Zaplatina // Herald of O.E. Kutafin University. 2020. № 4(68). P. 124.

[521] Kurzweil R. The Age of Intelligent Machines / R. Kurzweil. Cambridge, Mass.: MIT Press, 1990. P. 17.

[522] Borisov D.N. Op. cit. P. 27.

[523] Meldo A.A. Artificial intelligence in medicine: current state and main directions of development of intellectual diagnostics / A.A. Meldo, L.V. Utkin, T.N. Trofimova // Radiation diagnostics and therapy. 2020. Vol. 11. № 1. P. 10.

[524] Eidenmueller H. The Rise of Robots and the Law of Humans [Electronic resource] / H. Eidenmueller // Oxford Legal Studies Research Paper. 2017. Vol. 27. 15 p. doi: 10.2139/ssrn.2941001.

[525] Zueva A.I. Balance of interests of artificial intelligence and human capital in the digital economy: challenges and threats for sustainable development of business and economy / A.I. Zueva // Economy and society: modern development models. Vol. 11. № 1. P. 73.

[526] Malyshkin A.V. Integrating artificial intelligence into public life: some ethical and legal problems / A.V. Malyshkin // Vestnik SPbU. Law. 2019. Vol. 10. № 3. P. 446.

	Self-referential adaptation of one's behavior and decisions, autonomous deep self-learning, development of homologated «languages» of communication within oneself and with other AIs	Ponkin I.V., Redkina A.I., Malyshkin A.V., Zueva A.I.
	Analyzing and understanding one's own behavior and experiences, self-referentially making and implementing one's own decisions	Vasiliev A.A., Spoper D.; Eidenmueller H.
	Anthropomorphic-intelligent independent (including creative) decision-making and information processing using heuristic methods in the presence of several decision options	Morhat P.M.; Borisov D.N.; Kushnirchuk I.I.; Sevryukov V.V., Kovalenko E.I.; Chernykh E.E.[527]; Bakhin S.V.[528]
	Ability to solve loosely structured problems and predicate on the results of analyzing structured data sets	Zaplatina T.S.
	Substantivity	Ponkin I.V., Redkina A.I.
	Ability to creatively solve problems and create new information	Kamener L.[529], Sinelnikova V.N.[530]
	Autonomy (full or partial), including in decision-making, self-governance	Morhat P.M.; Ponkin I.V., Redkina A.I.; Malyshkin A.V.; Vasiliev A.A., Shpoper D.; Kolesnichenko O.Y., Kolesnichenko Y.Y., Litvak N.D.[531]; Borisov D.N., Kushnirchuk I.I., Sevryukov V.V., Kovalenko E.I.; Bakhin S.V.

We can notice that the concept of artificial intelligence often includes attributes that duplicate each other. Obviously, the definition of artificial intelligence, obtained as a result of combining these features (or most of them), is not functional due to its scope. In addition, not all of the designated features have legal significance and do not define the technology of artificial intelligence.

It follows from the above analysis that the most «popular» feature of AI is its autonomy. This property is also mentioned as an integral element of the technology in official documents, for example,

[527] Chernykh E.E. Main directions of strategies for the development of artificial intelligence in medicine. P. 74.

[528] Bakhin S.V. Artificial intelligence as a subject of law / S.V. Bakhin // Proceedings of the National (All-Russian) Conference on Natural Sciences and Humanities «SPbU Science – 2020» (St. Petersburg, December 24, 2020). St. Petersburg, 2021. P. 768-769.

[529] Kamener L. Courting change: the verdict on AI and the courts [Electronic resource] // CENTREFORPUBLICIMPACT.ORG: website of The Centre for Public Impact, a BCG Foundation, an independent education research and consulting firm dedicated to improving learning outcomes. 2017. 14 April. URL: https://www.centreforpublicimpact.org/courting-change-verdict-ai-courts (date of access: 30.05.2023).

[530] Sinelnikova V.N. Rights to the results of artificial intelligence / V.N. Sinelnikova, O.V. Revinsky // Copywriting. Bulletin of RAIS and RAO. 2017. № 4. P. 18.

[531] Kolesnichenko O.Y. Artificial intelligence in healthcare: system problems / O.Y. Kolesnichenko, Y.Y. Kolesnichenko, N.D. Litvak // Remedium. Journal of the Russian market of drugs and medical equipment. 2018. № 4. P. 25.

the 2018 report of the U.S. Congressional Research Service[532]. However, what we should understand by autonomy and autonomy of what exactly is assumed in this case – is not reported.

To overcome the chaotic nature of AI properties, let us turn to the existing definitions, which are provided by the existing sources of international, integration and domestic law, as well as enshrined in the official documents of non-state organizations.

First of all, to a specialized act of integration education – European Parliament Resolution № 2015/2103 of 16.02.2017, which deals with legal issues exclusively in the field of development and implementation of new technologies. We can quite reasonably attribute to AI some characteristics of smart robots, which are mentioned in item «Z» of the section «Responsibility» of EU Resolution № 2015/2103, namely: autonomy and realization of cognitive processes, among which stand out: the ability to learn and make quasi-independent decisions. At the same time, autonomy means independent decision-making and realization of decisions. In addition, paragraph 1 of Section «General Provisions...» specifies such properties as: the ability to exchange and analyze data, the presence of minimal physical support, adaptation of their actions to environmental conditions and the absence of biological life.

Given the intangible nature of AI, the presence of physical support should be considered as an optional attribute. In addition, instead of «absence of biological life», it would be more correct to point out the artificial nature of the origin of algorithms, i.e. their creation by a human being, which is not conditioned by biological necessity. Such a formulation will allow us to escape from the global discussion about what life is and from what point it arises.

A more detailed definition of AI is enshrined in non-legal normative documents. For example, paragraph 2(a) of the UNESCO Recommendation on the Ethical Aspects of AI of 2021 states that AI-based systems are information processing technologies that incorporate models and algorithms that provide the ability to learn and perform cognitive tasks, producing results in the form of predictive evaluation and decision-making in tangible and virtual environments. AI systems are designed to operate with some degree of autonomy through modeling and knowledge representation, as well as the use of data and the calculation of correlation relationships.

As we will see below, this definition contains several secondary properties that do not define AI technology (the nature of the result obtained – a predictive assessment or a decision in a certain environment – has no legal significance). At the same time, the indication of the ability to learn and perform cognitive functions is certainly a positive feature of this definition, as many sovereign or non-sovereign actors limit themselves to merely indicating that an AI system exhibits intelligent behavior or behavior

[532] Hoadley D., Lucas N. Artificial Intelligence and National Security [Electronic resource]: CRS report // UNT Digital Library: [website] / Congressional Research Service. 2018. 26 April. 42 p. URL: https://digital.library.unt.edu/ark:/67531/metadc1157028/m1/1/ (date of access: 30.05.2023).

indistinguishable from human behavior (an example of which is the definition found in the WMA's 2019 Statement on Augmented Intelligence in Medical Care).

Often the definition of AI is stated by listing specific tasks that can be performed by an algorithm or specifying its architecture (neural network, machine learning, etc.). An example of this is the definition set forth in IMDRF Technical Paper № IMDRF/AIMD WG/N67 «Machine Learning Enabled Medical Devices: Key Terms and Definitions» of 2022 or in the WCE FG-AI4H Focus Group Results of 2022 № DEL0.1 «Common Unified Terms for AI in Healthcare»[533]. This approach seems inappropriate to us: further development of smart technologies will necessitate further expansion of the concept, which will lead to unnecessary casuistry and its practical inapplicability.

The lack of further clarification of AI properties, such as cognitive tasks and learning (UNESCO) or autonomy (IMDRF)[534], leads to the need to analyze national laws. Thus, at the domestic level, attention should be paid to the concept of AI, which is contained in the National Strategy for the Development of AI until 2030. In accordance with par. «a», item 5 of the National Strategy, artificial intelligence is a set of technological solutions that allows imitating human cognitive functions (including self-learning and search for solutions without a predetermined algorithm) and obtaining results comparable to the results of human intellectual activity when performing tasks.

The positive feature of this definition is its brevity and accuracy – the constitutive feature of AI (realization of cognitive functions) is indicated. At the same time, the second part of the presented definition leads to a new unresolved question about what the results of human intellectual activity are. However, we can positively note the absence of mentioning the hardware component as an AI element in the disclosure of the term «complex of technological solutions».

In general, the presented definition is quite successful, as it reflects the nature of artificial intelligence to the greatest extent. Some researchers evaluate the presented definition of the concept as a reference one due to its universality[535]. At the same time, some features specified in the definition are secondary, and the content of cognitive functions and intellectual activity is not disclosed, which only gives rise to new, no less complex, questions.

The greatest theoretical interest in this context is represented by technical regulations and national standards, within the framework of which artificial intelligence has received the most detailed

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[533] Common unified terms in artificial intelligence for health: prepared by ITU-T Focus Group Deliverable 09.2022, № FG-AI4H DEL0.1 [Electronic resource] // ITU: [website] / Focus Group on Artificial Intelligence for Health № FG-AI4H of ITU Telecommunication Standardization Sector. URL: https://www.itu.int/dms_pub/itu-t/opb/fg/T-FG-AI4H-2022-1-PDF-E.pdf (date of access: 30.05.2023).

[534] See previously mentioned: Machine Learning-enabled Medical Devices: Key Terms and Definitions: Technical document. URL: https://www.imdrf.org/documents/machine-learning-enabled-medical-devices-key-terms-and-definitions (date of access: 30.05.2023).

[535] Privalov S.A. Artificial intelligence technologies in the sphere of ensuring the right to health protection, affordable and quality medical care: prospects and problems of regulation / S.A. Privalov // Vestnik of the SJSUA. 2021. № 4 (141). P. 38.

regulation. The GOST R 43.0.5-2009 «Information support of engineering and operator activity. Processes of information exchange in technical activity. General Provisions»[536] (hereinafter – GOST R 43.0.5-2009) contains a detailed description of the structure and principles of AI functioning, which, in our opinion, reveals the nature of the technology to the greatest extent.

According to p. 3.17 of GOST R 43.0.5-2009 artificial intelligence is a modeled (artificially reproduced) intellectual activity of human thinking, which confirms our argument about the immaterial nature of AI, which consists in certain thinking properties of the system. Unlike the normative acts mentioned earlier, GOST R 43.0.5-2009 reveals each of the elements of the concept: in it we can see the description of the structure of thinking processes and learn what thinking is about.

Thus, intelligence is understood as a subject's ability to abstract thinking and abstraction, which allows him/her to use the available information in a useful and purposeful way with the emergence of self-consciousness and reflection (p. 3.10 of GOST R 43.0.5-2009). According to the results of the analysis of p. 3.24 of GOST R 43.0.5-2009 we will come to the conclusion that thinking is reduced to (1) thinking activity, (2) connected with realization of information-exchange processes. In its turn, thinking activity conditionally consists of the results of such activity (perceptions, judgments, inferences, etc.) and its subtypes: disside, clearartive and creative activity (p. 3.23 of GOST R 43.0.5-2009), which are understood to be:

— disidiosis – making a decision on the necessary use (with possible transformation) of information stored in memory or perceived from the external environment;

— cliaratiosis – understanding of information used with possible consideration of information perceived and stored in memory;

— creatioisis – creative transformation of information stored in memory with possible consideration of perceived information.

The very ability to obtain certain reasoning or inferences as a result of thought processes and to incorporate such inferences into one's own experience is cognitiosis. Conventionally, we can designate this phenomenon as a cognitive property (function) of intelligence – a feature of artificial intelligence, which is often mentioned in scientific literature without disclosing its content.

The terminological sequence of GOST R 43.0.5-2009 seems to us to be the most successful solution, as it allows us to step by step build a coherent and consistent legal understanding of such a complex category as thinking. Earlier we could see a wide range of different, often synonymous, formulations of AI ability to carry out thinking processes.

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[536] GOST R 43.0.5-2009. Information support of technical and operator activity. Processes of information-exchange in technical activity. General provisions [Electronic resource] ; introduced 2011-01-01 // Feder. agency on technical regulation and metrology: [website]. Moscow, 2010. URL: https://protect.gost.ru/v.aspx?control=8&baseC=6&page=0&month=5&year=2022&search=43.0.5-2009&RegNum=1&DocOnPageCount=15&id=168130 (date of access: 30.05.2023).

The use of the terms «reasonable», «cognitive», «intellectual», «intelligence», «mental» and «thinking» actually denote the possibility of realization of certain thought processes. Attempts by legislators and researchers to list such processes, in turn, suffer from haphazardness and result in the presentation of an extensive list of methods of cognition (analysis, generalization, modeling), certain types of thinking activity (evaluation, learning, perception, recognition of images, symbols), as well as phenomena whose nature is not defined at all (reflexion, self-consciousness, imaginative thinking, creativity), which obviously only complicates the question of the legal nature of artificial intelligence.

This situation is caused by the lack of a clear understanding of the terms used and the desire to cover the widest possible range of phenomena and processes attributed to intelligence. At the same time, the designated list, when examined more closely, is almost completely covered by the three mentioned types of thinking activity (cleararative, disside and creative).

Thus, to qualify a system as a carrier of artificial intelligence, it must be established that an algorithm can purposefully:

— independently process information, i.e. transform data using the means and methods of cognitive activity;

— to make decisions, both intermediate (aimed at selecting means and methods of information processing) and final decisions;

— understand the information being processed, i.e. classify data, determine its content and form, and relate such data to possible means and methods of processing;

— to process information creatively, i.e. to come to results that were not prescribed by developers in advance, but can be derived from the means and methods of data processing, principles and rules of algorithm operation, taking into account its experience (processing results and their evaluation both by the system itself and by the developers based on the results of training).

In their totality, the presented features provide autonomy as a key legal property of artificial intelligence. This attribute presupposes autonomy of thinking activity, so the nature of AI is not defined through independence from power sources, other programs, hardware component, freedom of movement, independent goal-setting or selective subordination to a human being.

Other attributes, in our opinion, are secondary. Thus, many authors define AI through the form of existence, indicating that it should be virtual, cyberphysical, electronic-mechanical, etc. However, we pointed out that the hardware component, as well as another form of «objectification», does not predetermine the nature of artificial intelligence, since it does not affect its thought processes. It is the «man-made» nature of technology creation that is of fundamental importance.

In continuation of this argument, a number of authors emphasize the presence of a technical device for perception and transmission of information, interaction with the environment (cyberphysical

system) as a feature of AI[537], or in general the ability of AI to affect the environment is indicated[538]. In our opinion, this feature leads to the confusion of artificial intelligence as an autonomous cognitive system with the hardware environment in which such an algorithm functions.

Intelligence is a certain property of an algorithmic structure that gives its activity a purposeful character, but it is not a mechanical shell at all. Similarly, attempts to single out as a property the ability of an algorithm to interact with the surrounding world, to exchange data, are untenable. We do not deny that some systems include mechanical elements that allow to influence the environment. However, this component is optional, and in its absence a certain technical solution will not lose its AI properties.

Special attention should be paid to the repeated mentioning by researchers of the anthropomorphic nature of AI thought processes and their imitative nature. This position is a consequence of anthropocentrism, aimed at postulating the unique position of man among other elements of the surrounding reality. This concept, which is characteristic of law in general, prevents the objective study of artificial intelligence, to which they seek to attribute human characteristics (so-called anthropomorphism)[539]. A legally significant property of AI is the autonomy of its thinking activity, by which we understand a certain set of properties of computational processes without any indication of their human nature.

This position is shared by the researchers who were at the origins of AI science. Thus, J. McCarthy, being the author of the term in question (first mentioned in 1955 as part of the «Dartmouth Summer Research Project on Artificial Intelligence»[540]), notes that the main issue concerning the nature of AI is a misunderstanding of what exactly computational processes should be labeled as «intelligent»; therefore, intelligence within the framework of the relevant science was considered solely as a computational aspect of a system's ability to solve certain tasks[541].

By denoting a concept through a set of features with autonomous content, a certain matrix of scientific knowledge is created, which should not coincide with the real characteristics of the object under study[542] – and legal science is no exception. Pointing to the anthropomorphic nature of AI is perceived as an attempt to avoid the question of the nature of intelligence and thinking through their identification with human intelligence and thinking, which deceptively seem to us intuitively more understandable categories.

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[537] Morhat P.M. Artificial Intelligence: A Legal Perspective. P. 43-44.

[538] Zueva A.I. Op. cit. P. 73.

[539] Sharkey A. Artificial Intelligence and Natural Magic / A. Sharkey, N. Sharkey // Artificial Intelligence Review. 2006. Vol. 25. № 1-2. P. 9-19.

[540] A Proposal for the Dartmouth Summer Research Project on Artificial Intelligence. August 31, 1955 / J. McCarthy [et al.] // AI Magazine. 2006. Vol. 27. № 4. P. 12-14.

[541] McCarthy J. What is Artificial Intelligence? [Electronic resource] / J. McCarthy. Palo Alto: Stanford University, 2007. URL: http://www-formal.stanford.edu/jmc/whatisai/whatisai.html (date of access: 30.05.2023).

[542] Arkhipov S.I. Subject of law : a theoretical study / S.I. Alekseev. SPb.: Legal Center Press, 2004. P. 120.

The next group of semantically identical features combines self-referentiality, self-regulation, self-adaptation to changing conditions, self-restraint, independent modeling, correcting algorithms of actions and maintaining itself in homeostasis. In part, these characteristics express the ability of AI to change its behavior depending on a set of external and internal factors. In our opinion, this process is fully covered by the following features:

— learnability as implementation in AI of data processing tools and methods, principles and rules of work on the basis of a marked-up dataset with indication of the correct solution;

— self-learning as creation by the AI itself of new tools and methods of data processing, principles and rules of operation as a result of its own thinking activity based on experience (implemented or acquired).

Since learnability is directly related to the processes of data accumulation and processing, such a feature covers the abilities to learn, accumulate, reproduce information and experience, and genetic search. It should be taken into account that algorithms are not in all cases trained and self-trained during their life cycle. At certain stages of development, for example, during technical tests, this function may be disabled in order to fix specific performance indicators of the system, which, however, should not affect the legal nature of the technology.

In scientific literature, there is also a position according to which AI should have the ability to self-reproduction and collective generation of ideas with the help of its copies; high speed of computation; the ability to work continuously; the ability to simulate friendship, joy and other feelings, emotions and states inherent in humans[543]. Almost all of these properties are not related to cognitive processes and can be detected in many existing computer programs (viruses, chatbots, etc.), which are devoid of any autonomy.

Finally, let us consider substantivity (or subjectivity) as a feature of AI. The problem of legal personality of algorithms affected by this property is one of the most debatable issues within the framework of the legal regime of artificial intelligence. We cannot include the legal status of the object of regulation as its attribute, because the status of AI (1) can change repeatedly, (2) does not affect the legal nature of the considered phenomenon.

Thus, based on the analysis of the legal framework and doctrine, we can form the following definition of the concept of technology:

Artificial intelligence is an artificial computer system that is capable of autonomous thinking activity, i.e. to independently perceive, understand and process information, including using algorithms created (modified) by the system itself, to make intermediate (procedural) and final decisions not prescribed in advance, to learn and self-learn on the basis of experience.

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[543] Radutniy O.E. Criminal Liability of the Artificial Intelligence / O.E. Radutniy // Problems of Legality. 2017. № 138. P. 138.

This definition covers all primary characteristics of AI, directly or indirectly. The inclusion of additional characteristics would lead to unnecessary casuistry without actually improving the functionality and legal-technical properties of the definition. Our conclusions are based on a clear categorization of the phenomena under consideration, each of which was endowed with its own content, thus avoiding unnecessary descriptiveness and duplication of semantic elements. In addition, this definition of the concept is unified, as it can be applied to any artificial intelligence carriers regardless of their functional purpose, including the field of medicine.

Having formed the concept of artificial intelligence, we can touch upon the problem of its correlation with natural intelligence. For legal research and legal regulation any object is considered as a set of its legal properties. In this regard, the indicated problem is reduced to the question of similarities and differences of legal features of artificial and natural intelligence. At the same time, natural intelligence itself (not counting the results of its activity) has not been practically the object of regulation or legal research, and there is no corresponding legal term. In this regard, we cannot correlate the designated phenomena, at least not without forming the concept of natural intelligence, which is beyond the scope of this paper.

Let us limit ourselves to the most obvious difference, which is the origin of intelligence and the basis of its functioning (hardware-computer or biochemical). At the same time, we can state the conditional identity of artificial and natural intelligence, since both are capable of carrying out autonomous thinking activity.

Some researchers note that the very inclusion of the word «intelligence» in the term denoting technology is incorrect and untimely, since it is impossible to technically embody all the properties of intelligence. In this regard, it is more appropriate to use the wording «the effect of artificial thinking»[544]. In our opinion, this position is hardly of practical and theoretical significance in the field of law, where we are guided exclusively by the legal properties of phenomena that cannot go beyond the objective limits of legal regulation. The term «intelligence» should not include all the properties of its real «analog». In our opinion, there are prerequisites for the formation of a universal concept of intelligence as a set of cognitive properties that can be inherent in objects of both natural (biological) and artificial origin

[544] Zueva A.I. Op. cit. P. 74.

CORRELATION OF ARTIFICIAL INTELLIGENCE WITH RELATED TECHNOLOGIES

1. Robots

Often in the texts of scientific papers there is a mixing of the relevant categories[545]. The difference between AI and robots is quite clear: artificial intelligence is a set of certain properties of computational processes without reference to the hardware component, while the key properties of a robot are (1) the presence of a hardware-software complex[546] for information perception, physical interaction, and (2) its «spatial» autonomy[547]. The robot is able to act automatically[548], i.e. to function according to programmed patterns, which is qualitatively different from the autonomy of artificial intelligence.

The combination of AI and robot in one technical solution is possible if the software of such a robot exhibits the corresponding properties. An object combining these technologies is usually called a «smart robot». We will find confirmation of our position in GOST R 60.0.0.4-2019 «Robots and robotic devices. Terms and definitions»[549], according to p. 2.6 of which a robot is an executive mechanism, programmable by two or more degrees of mobility, possessing a certain degree of autonomy and capable of moving in the external environment in order to perform tasks as intended. This standard contains in clause 2.28 the category «adaptive robot», which means a robot capable of performing tasks by perceiving and changing the external environment and/or interacting with external sources and adapting its behavior.

It is noteworthy that in the terminology of ISO 8373:2012 «Robots and robotic devices – Vocabulary», to which the GOST under consideration is identical, the term «adaptive robot» corresponds to the term «intelligent robot». In this regard, the presented wording describes exactly the «intelligent robot», the key feature of which is the adaptability of behavior. The previously valid GOST R ISO 8373-

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[545] Petit N. Law and Regulation of Artificial Intelligence and Robots – Conceptual Framework and Normative Implications [Electronic resource] / N. Petit // SSRN Electronic Journal. 2017. 31 p. doi: 10.2139/ssrn.2931339.

[546] Keisner A. Robotics: Breakthrough Technologies, Innovation, Intellectual Property / A. Keisner, J. Raffo, S. Wunsch-Vincent // Foresight and STI Governance. 2016. Vol. 10. № 2. P. 7-27.

[547] Arkhipov V.V. Artificial intelligence and autonomous devices in the context of law: on the development of the first Russian Law on Robotics / V.V. Arkhipov. Arkhipov V.V., Naumov V.B. // Proceedings of SPIIRAS. 2017. № 6. P. 46-62; Filipova I.A. Legal regulation of artificial intelligence: regulation in Russia, foreign research and practice / I.A. Filipova // State and Law. 2018. № 9. P. 82; Calo R. Robotics and the Lessons of Cyberlaw / R. Calo // California Law Review. 2015. Vol. 103. № 3. P. 513-563.

[548] Baranov P.P. Op. cit. P. 41.

[549] GOST R 60.0.0.4-2019 / ISO 8373:2012 [Electronic resource]. Robots and robotic devices. Terms and definitions ; introduced 2019-09-01 // Federal Agency for technical regulation and metrology: [website]. Moscow, 2019. URL: https://protect.gost.ru/v.aspx?control=8&baseC=6&page=0&month=5&year=2022&search=ГОСТ%20Р%2060.0.0.4-2019&RegNum=1&DocOnPageCount=15&id=224619 (date of access: 30.05.2023).

2014 «Robots and robotic devices. Terms and Definitions»[550] used the term «intelligent robot; robot with AI elements», which seems to us to be more successful.

Thus, robots and AI are conceptually distinct categories. If they are combined, we are talking about the emergence of so-called «intelligent robots», which some authors propose to eloquently distinguish into the category of *robo-sapiens*, «intelligent robot»[551]. Identification of «intelligent robots» is of great legal importance, as it is the basis for extending the legal regime of AI to such devices[552].

2. Cyberphysical systems

It is often noted by authors that AI manifests itself through the cyberphysical system, which is its integral element. The question of the correlation of these concepts arises. The cyberphysical system is a set of software and physical components that carry out the computational processes of such software[553].

Since a cyberphysical system includes software, i.e. a certain computer algorithm, there is a risk of confusing this concept with AI. At the same time, AI manifests itself through certain cognitive properties of computational processes, while a cyberphysical system is a «shell» in which the relevant computations are performed. Thus, the question of synonymity of cyberphysical system and AI cannot arise – both categories have their own functional content.

3. Neural networks

Let us consider the issue of distinguishing between AI and neural networks. Neural networks aim to improve human-machine communications and are based on an architecture that copies the structure and principles of the brain, including the behavior of neurons[554], or the nervous system of living organisms[555]. Neural network data processing is performed on several «simple» computational layers, similar to neurons, which receive input data, process it and pass it to the next «neuron» like axons[556].

We can find confirmation of this approach in the following acts:

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[550] GOST R ISO 8373-2014. Robots and robotic devices. Terms and definitions [Electronic resource] ; introduced 2016-01-01 // Reference legal system «Codex». Moscow, 2015. URL: https://docs.cntd.ru/document/1200118297 (date of access: 30.05.2023).

[551] Laptev V.A. Op. cit. P. 89.

[552] Iriskina E.N. Legal aspects of civil liability for causing harm by actions of a robot as a quasi-subject of civil-law relations / E.N. Iriskina, K.O. Belyakov // Humanitarian Informatics. 2016. № 10. P. 65.

[553] Laptev V.A. Op. cit. P. 82.

[554] Canadian Association of Radiologists White Paper on Artificial Intelligence in Radiology / A. Tang [et al.]. // Canadian Association of Radiologists Journal. 2018. Vol. 69. № 2. P. 120-135.

[555] Yastrebov O.A. Legal personality of an electronic person: theoretical and methodological approaches / O.A. Yastrebov // Proceedings of the Institute of State and Law of the Russian Academy of Sciences. 2018. Vol. 13. № 2. P. 41.

[556] Mel'nikov P.V. Op. cit. P. 61.

— Presidential Decree № 1661 of 17.12.2011[557], according to the provisions of which (p. 2 of the Technical Notes to Category 4.1 of Section 1 of the List) «neural computer» is a computing device designed or modified to simulate the behavior of a neuron or a set of neurons;

— GOST R 59525-2021[558], which states in clause 3.1.17 that a neural network is a network of elements of simple processing connected by weighted links, in which each element produces a value by applying a nonlinear function and passes it to other elements or presents it as an output value.

The presented definition allows us to consider a neural device as (1) a certain type of structure and principles of functioning (architecture) of a computing system, (2) which is capable of processing information using nonlinear methods. In the part related to learning, neurotechnologies overlap with AI. At the same time, not every neural network exhibits AI properties.

Taking into account the doctrinal understanding of neurotechnologies, it seems reasonable to assert that a neural network is one of the types of architecture on the basis of which a particular AI system can function. At the same time, the mere fact of using neurotechnologies for computing does not predetermine the realization of cognitive functions, which should be established separately.

There are several types of neural networks, the most interesting of which are the so-called deep neural networks. The most effective, especially in the field of analysis of diagnostic images and other high-dimensional data[559], are convolutional neural networks, which incorporate unsupervised deep learning mechanisms[560] and generalize and transform the data according to their own criteria during processing on the basis of linear transformation[561]. Examples of relevant neural networks are Convolutional Deep and Wide Network (CDWN)[562], U-Net[563], Convolutional-Deconvolutional Neural Networks (CDNN)[564], iW-Net[565] and SegNet[566].

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[557] On Approval of the List of dual-use goods and technologies that can be used in the development of weapons and military equipment and in respect of which export control is exercised : Presidential Decree № 1661 of 17.12.2011, ed. of 19.02.2021. // CL RF. 2011. № 52. Art. 7563.

[558] GOST P 59525-2021. Health informatization. Intellectual methods of medical data processing. Basic provisions [Electronic resource] ; introduced 2022-01-01 // Federal Agency for technical regulation and metrology: [website]. Moscow, 2021. URL: https://protect.gost.ru/v.aspx?control=8&baseC=6&page=0&month=5&year=2022&search=59525-2021&RegNum=1&DocOnPageCount=15&id=230334 (date of access: 30.05.2023).

[559] Artificial intelligence in healthcare: past, present and future / F. Jiang [et al.] // Stroke and Vascular Neurology. 2017. Vol. 2. № 4. P. 230-243.

[560] Antoniades Ch. Op. cit. P. 116.

[561] Borisov D.N. Op. cit. P. 28.

[562] Agnes S.A. Automatic lung segmentation in low-dose chest CT scans using convolutional deep and wide network (CDWN) / S.A. Agnes, J. Anitha, J.D. Peter // Neural Computing and Applications. 2020. Vol. 32. № 4. P. 15845–15855.

[563] Ronneberger O. U-Net: Convolutional Networks for Biomedical Image Segmentation [Electronic resource] / O. Ronneberger, P. Fischer, T. Brox // ARXIV.ORG: A free distribution service and an open-access archive. arXiv: 1505.04597v1 [cs.CV]. 2015. URL: https://arxiv.org/pdf/1505.04597.pdf (date of access: 30.05.2023).

[564] Ben-Cohen A. Fully convolutional network for liver segmentation and lesions detection / A. Ben-Cohen [et al.] // Lecture Notes in Computer Science. 2016. Vol. 10008. P. 77–85. doi: 10.1007/978-3-319-46976-8_9.

[565] IW-Net: an automatic and minimalistic interactive lung nodule segmentation deep network [Electronic resource] / G. Aresta [et al.] // Scientific Reports. 2019. Vol. 9. № 1. 7 p. doi: 10.1038/s41598-019-48004-8.

[566] Badrinarayanan V. SegNet: A deep convolutional encoder-decoder architecture for image segmentation / V. Badrinarayanan, A. Kendall, R. Cipolla // IEEE Transactions on Pattern Analysis and Machine Intelligence. 2017. Vol. 39. № 12. P. 2481–2495.

Such neural networks are based on processing in several stages (convolution and pooling) and computation on multiple hidden layers, which results in data dimensionality reduction with the selection of the most significant elements[567]. AI based on this architecture is the least transparent due to the «multilayer» nature of computational processes, which creates an opportunity for uncontrolled learning.

4. Machine learning

Machine learning (hereinafter – ML) or data mining[568] refers to (1) technologies based on the use of mathematical data models to train a program without direct instructions on the basis of solving a set of similar problems, as well as (2) the section of scientific knowledge devoted to the development of appropriate algorithms for data processing[569]. The essence of MO algorithms is to identify data patterns and build predictive models[570] on their basis with minimal human involvement[571].

These algorithms can be represented by other technologies, usually neural networks. It is thanks to neurotechnology that deep learning, one of the most technically challenging forms of AI, is possible[572]. In fact, machine learning is a technological component of AI. In this regard, machine learning is called a method[573], subset, form[574], subsection[575] or area[576] of AI, in some cases fully identifying these technologies[577]. We believe it is possible to identify machine learning and learning as one of the cognitive properties of AI.

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[567] Nikolenko P. Deep learning. Immersion in the world of neural networks / S. Nikolenko, A. Kadurin, E. Arkhangelskaya. SPb.: Peter, 2018. 480 p.

[568] Klimontov V.V. Op. cit. P. 157.

[569] Mukhamadiev R.R. Development of the project management system from the position of efficiency / R.R. Mukhamadiev, N.A. Staroverova, M.L. Shustrova // South-Siberian Scientific Bulletin. 2019. № 1 (25). P. 187-192.

[570] What is machine learning? [Electronic resource] // AZURE.MICROSOFT.COM: Azure cloud platform website. [2022]. URL: https://azure.microsoft.com/ru-ru/overview/what-is-machine-learning-platform/#techniques (date of access: 30.05.2023); Next-Generation Machine Learning for Biological Networks / D.M. Camacho [et al.] // Cell. 2018. Vol. 173. № 7. P. 1581-1592.

[571] Rayner K. Eye movements in reading and information processing: 20 years of research / K. Rayner // Psychological Bulletin by the American Psychological Association. 1998. Vol. 124. № 3. P. 372-422.

[572] What is machine learning? // URL: https://azure.microsoft.com/ru-ru/overview/what-is-machine-learning-platform/#techniques (date of access: 30.05.2023).

[573] Meldo A.A. Op. cit. P. 10.

[574] What is machine learning? // URL: https://azure.microsoft.com/ru-ru/overview/what-is-machine-learning-platform/#techniques (date of access: 30.05.2023).

[575] Mukhamadiev R.R. Op. cit. P. 187-192.

[576] Zuikova A. What is machine learning and how it works [Electronic resource] // TRENDS.RBC.RU: network edition «RBC Trends». 2021. 15 June. URL: https://trends.rbc.ru/trends/industry/60c85c599a7947f5776ad409 (date of access: 30.05.2023).

[577] Melnikov P.V. Op. cit. P. 61.

Appendix D

ROC AUC AS THE MOST EFFECTIVE AI METRIC

ROC AUC (ROC – Receiver Operating Characteristic, AUC – Area Under Curve) is one of the most popular combined metrics used to evaluate the performance of artificial intelligence systems. This metric is defined by the area covered by a curve. The corresponding curve is plotted on a graph, the axes of which are the following indicators[578]:

– TPR (True Positive Rate), which is represented by the formula: TP / (TP + FN), i.e. it is actually the sensitivity (Recall) and represents the ability to detect a certain class of phenomena, where the maximum value of 1 indicates that the algorithm correctly identified all true positive cases;

– FPR (False Positive Rate), which is represented by the formula: FP / (FP + TN), i.e. it represents the ability of the system to detect negative classes of phenomena, where the maximum value of 1 indicates that the algorithm has not detected any true negative cases.

The ROC AUC will be the area directly under this curve. In this case, the 45° line on the graph represents the value of FPR = TPR, which in practice means that the AI determines the presence or absence of a fact with a probability of 50%, in other words, completely randomly. Accordingly, the best performance is achieved when the curve tends towards the value of TPR = 1, FPR = 0, i.e. the point at the top left when AUC = 1 (100%). An example display of the ROC AUC metric is shown in the image below (figure 1).

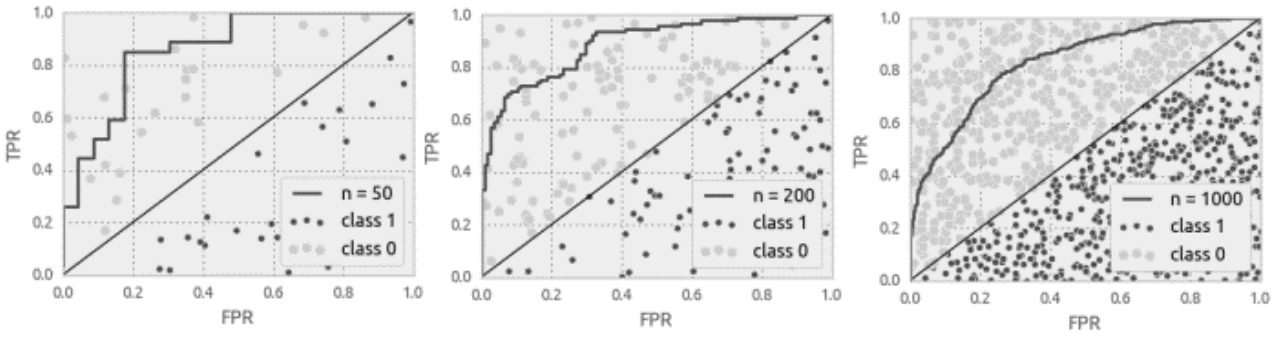

Figure 1. ROC AUC curve

The ROC curve allows comparing several AI systems or different settings of the same algorithm based on the balance between the number of reliable predictions about the presence or absence of a certain fact, for example, pathology. Due to its combinatorial nature, an additional advantage of ROC

[578] Huang J. Using AUC and Accuracy in Evaluating Learning Algorithms / J. Huang, Ch.X. Ling // IEEE Transactions on Knowledge and Data Engineering. 2005. Vol. 17. № 3. P. 299-310.

AUC stands out due to its high predictive value[579]. In addition, the clear visualization of this metric contributes to the transparency of the algorithm and can be used, among other things, to inform patients.

[579] Abramov R. Basic metrics of classification tasks in machine learning [Electronic resource] // WEBIOMED.AI: official website of the system of predictive analytics and patient risk management «Webiomed». 2020. July 8. URL: https://webiomed.ru/blog/osnovnye-metriki-zadach-klassifikatsii-v-mashinnom-obuchenii/ (date of access: 30.05.2023).

Appendix E

INFORMATION SYSTEMS AT INTERNATIONAL AND NATIONAL LEVEL

Internationally, there is no single database, information system or prototype within a particular field of application. We will only find examples of the most successful open databases developed by individual medical organizations, research teams or non-profit associations. Examples of such databases are: LIDC (Lung Image Database Consortium image collection), which contains training and test datasets in CT diagnosis of lung cancer[580]; BraTS (Brain Tumor Segmentation) – an annually published dataset containing labeled MR images of the brain for tumor diagnosis[581]; LiTS (Liver Tumor Segmentation Challenge) – a database of CT images of the liver for tumor diagnosis[582]; PTB-XL – the largest database containing ECG studies (over 21,000 records)[583]; CPTAC-CCRCC (Clinical Proteomic Tumor Analysis Consortium Clear Cell Renal Cell Carcinoma) – dataset combines the results of radiological studies of renal tumors[584]; HAM10000 (Human Against Machine with 10000 training images) – dataset containing skin images for pathology diagnosis[585], etc.

[580] LIDC-IDRI [Electronic resource]: database of diagnostic and screening chest images, computed tomography of lung cancer with annotated lesions // The Cancer Imaging Archive (TCIA): [website] / The National Cancer Institute ; The Foundation for the National Institutes of Health. [Little Rock.], 2011-2021. URL: https://wiki.cancerimagingarchive.net/display/Public/LIDC-IDRI (date of access: 30.05.2023); The lung image database consortium (LIDC) and image database resource initiative (IDRI): a completed reference database of lung nodules on CT scans / Armato III S.G. [et al.] // Medical Physics. 2011. Vol. 38. № 2. P. 915–931.

[581] Brain Tumor Segmentation (BraTS) 2021 [Electronic resource]: brain tumor segmentation database published from the annual competition held by the Perelman School of Medicine at the University of Pennsylvania // Brain Tumor Segmentation: [website] / Radiological Society of North America (RSNA) ; The American Society of Neuroradiology (ASNR) ; The Medical Image Computing and Computer Assisted Interventions (MICCAI). [Philadelphia], 2021. URL: http://braintumorsegmentation.org/ (date of access: 30.05.2023); The Multimodal Brain Tumor Image Segmentation Benchmark (BRATS) / B.H. Menze [et al.] // IEEE Transactions on Medical Imaging. 2015. Vol. 34. № 10. P. 1993–2024.

[582] LiTS [Electronic resource]: liver tumor segmentation database // CodaLab Competitions: [website] / 20th International Conference on Medical Image Computing and Computer Assisted Intervention (MICCAI) 2017. Quebec, 2017. URL: https://competitions.codalab.org/competitions/17094 (date of access: 30.05.2023); The Liver Tumor Segmentation Benchmark (LiTS) [Electronic resource] / P. Bilic [et al.] // ARXIV.ORG: A free distribution service and an open-access archive. arXiv:1901.04056 [cs.CV]. 2019. URL: https://arxiv.org/pdf/1901.04056.pdf (date of access: 30.05.2023).

[583] PTB-XL, a large publicly available electrocardiography dataset [Electronic resource] / P. Wagner [et al.] // Scientific Data. 2020. Vol. 7. № 1. doi: 10.1038/s41597-020-0495-6).

[584] CPTAC-CCRCC [Electronic resource]: database of cancer tumor images for genomic and proteomic studies // The Cancer Imaging Archive (TCIA): [website] / National Cancer Institute's Clinical Proteomic Tumor Analysis Consortium Clear Cell Renal Cell Carcinoma (CPTAC-CCRCC). [Bethesda], 2018-2022. URL: https://wiki.cancerimagingarchive.net/display/Public/CPTAC-CCRCC (date of access: 30.05.2023).

[585] Tschandl P. The HAM10000 dataset, a large collection of multi-source dermatoscopic images of common pigmented skin lesions [Electronic resource] / P. Tschandl, C. Rosendahl, H. Kittler // Scientific Data. 2018. Vol. 5. № 1. 10 p. doi: 10.1038/sdata.2018.161.

No less attention should be paid to existing services for searching and/or hosting publicly available databases, including medical databases, which enable international exchange of data and experience. Examples of such services are Kaggle[586], Papers with Code[587] and Google Dataset Search[588].

In Russia, the foundation for a unified clinical data base has been laid: in 2018, the Unified State Information System in Healthcare («EGISZ») became operational[589], the legal regime of which is regulated in Article 91.1 of Federal Law № 323-FZ «On the Fundamentals of Public Health Protection» and the Regulation on EGISZ, approved by Resolution of the Government of the Russian Federation № 555 dated 05.05.2018[590] (hereinafter – the Regulation). Analyzing the composition of EGISZ specified in clause 4 of the Regulation, we do not find any mention of PACS as one of the subsystems of the Unified System. At the same time, Section 2 of the Concept for the creation of the Unified System, approved by Order of the Ministry of Health and Social Development of Russia № 364 of 28.04.2011[591], points to the need to integrate medical equipment with medical information systems and the introduction of digital systems for the acquisition, diagnosis and archiving of medical images and data, which is PACS. At the moment, there is no single all-Russian PACS system, as well as no other single database on a national scale[592], but the regulation of the need to create such an information subsystem as part of the EGISZ, albeit within the framework of the concept, gives hope for the development of such a system in the near future.

There are prerequisites for the creation of a nationwide PACS system – at the moment there are already technological solutions on a regional scale, an example of which is the Central Archive of Medical Images (CAMI) created by NIPK «Elektron», which is functionally compatible with EGISZ[593]. Another example is the Unified Radiology Information Service (ERIS), a regional project, which is Russia's largest radiology information system, which since 2015 has integrated radiology diagnostic data from 162 medical institutions[594].

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[586] Kaggle [Electronic resource]: the world's largest community of data specialists / Kaggle Inc. [San Francisco, 2010]. URL: https://www.kaggle.com/ (date of access: 30.05.2023).

[587] Papers with Code [Electronic resource]: a platform for posting research results, data, and software code to promote machine learning, organized by a group of private developers working in the M*ta AI laboratory / M*ta Platform Inc. [Menlo Park, 2021]. URL: https://paperswithcode.com/ (date of access: 30.05.2023).

[588] Dataset Search [Electronic resource]: Google dataset search service // Google: [website]. [Mountain View, 2018]. URL: https://datasetsearch.research.google.com/ (date of access: 30.05.2023).

[589] EGISZ [Electronic resource]: Unified state information system in the field of health care / Ministry of Health of the Russian Federation. [Moscow], 2017. URL: https://egisz.rosminzdrav.ru/ (date of access: 30.05.2023).

[590] On a unified state information system in the field of health care : Resolution of the Government of the Russian Federation of 05.05.2018 № 555, ed. of 14.12.2021 // CL RF. 2018. № 20. Art. 2849.

[591] On approval of the Concept of creating a unified state information system in the field of health care: Order of the Ministry of Health and Social Development of Russia from 28.04.2011 № 364, ed. from 12.04.2012 // Bulletin of Labor and Social Legislation of the Russian Federation. 2011. № 7.

[592] Chelysheva N.Y. Op. cit. P. 18.

[593] CAMI [Electronic resource] : Central archive of medical images / a joint stock company «Research and Development Production Company «Elektron». [Moscow, 2019]. URL: https://electronxray.com/products/it-solutions/tsentralnyy-arkhiv-meditsinskikh-izobrazheniy.php (date of access: 30.05.2023).

[594] ERIS [Electronic resource]: Unified radiological information service // Center of diagnostics and telemedicine: [website] / GBUZ Scientific and Practical Clinical Center for Diagnostics and Telemedicine Technologies of the Department

Accordingly, at present we see a clear trend towards the creation of medical information systems of different levels in Russia, including within the framework of the national project «Health»[595]. Section 4.7 of the national project separately provides for the federal project «Creation of a single digital circuit in health care based on EGISZ», the essence of which is the wide distribution and implementation of medical information systems of federal, regional and local levels, which at the final stage of the project are proposed to unite, which is called «a single digital circuit in health care».

It should also be noted that there are already existing measures taken by the Russian legislator to create medical databases. In this context of interest is the federal integrated electronic medical record (a subsystem of the EGISZ), which according to clause 14 of the Regulation provides: (1) receipt, verification, processing and storage of structured anonymized clinical data; (2) creation of databases of anonymized information on certain categories of diseases and profiles of medical care. It is separately noted that the federal integrated electronic medical record is intended to support the development of AI projects through storage of anonymized medical data sets, support for markup and preparation of data sets, and verification. For this reason, the above subsystem is one of the most valuable elements of the EGISZ, which stimulates AI developments and contributes to improving the quality of algorithms' performance.

of Health of Moscow. Moscow, 2015. URL: https://tele-med.ai/proekty/edinyj-radiologicheskij-informacionnyj-servis_2020 (date of access: 30.05.2023).

[595] Passport of the national project «Health Care» : Minutes of 24.12.2018 № 16, approved by the Presidium of the Presidential Council for Strategic Development and National Projects [Electronic resource] // Government of Russia: [website]. Moscow, 2019. 11 February. URL: http://static.government.ru/media/files/gWYJ4OsAhPOweWaJk1prK-DEpregEcduI.pdf (date of access: 30.05.2023).