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International legal regulation of the use of artificial intelligence in the health care sector

Abstract. *The use of artificial intelligence technologies in healthcare offers truly impressive prospects. At the same time, the healthcare industry is traditionally and reasonably conservative. Many applications of technologies and products, from drugs to innovative solutions, require state control and management through legal regulation. In this article, we have listed some important regulatory legal acts (RLAs) that somehow govern the use of AI in healthcare. The article analyzes the international legal norms regarding the use of artificial intelligence in the field of health both at the international and national levels. The review examines the problems of using artificial intelligence in various fields of medicine, such as the diagnosis of diseases, recommendations for their treatment, and administrative activities in healthcare. The article analyzes prospects for the development of AI, conflicting views, and potential pitfalls in its implementation.*

Keywords: *artificial intelligence, machine learning, healthcare, human rights, legal regulation, WHO.*

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Introduction

Digital technology, machine learning and artificial intelligence (AI) are revolutionizing the fields of medicine, research, and the healthcare system. With great promise, this rapidly evolving area raises ethical, legal, and social challenges. For example, with respect to equal access, privacy, proper use and users, accountability, bias, and inclusiveness. These challenges are transnational in that the collection, exchange, and use of data generated or used by these technologies transcend national boundaries. The tools, techniques,

and technologies used in big data and artificial intelligence are being applied to improve services and health systems. However, many questions about the ethical development and use of these technologies remain unanswered, including the benefits that low- and middle-income countries will get from AI development.

Over the past decade, increased computing power and the availability of large amounts of data have prompted the practical use of artificial intelligence in the healthcare industry. Health and medical journals now typically include reports on machine learning and big data, as

well as descriptions of the risks associated with this technology and the management needed to manage it. Machine learning algorithms are used to diagnose, define treatments, and analyze public health threats, and these systems can continually learn and improve in response to new data. Artificial intelligence and machine learning have begun to be used in medicine to determine the diagnosis.

It takes years of medical training to properly diagnose diseases. Even so, diagnosis is often difficult and time-consuming. In many areas, the demand for experts far exceeds the available supply. This puts doctors in a quandary and often postpones the vital diagnosis of the patient. Machine learning algorithms have recently made huge strides in the automatic diagnosis of diseases, making diagnosis cheaper and more accessible.

Methodology

The current research work involves the analysis of laws and statutory instruments of different countries and international organizations in the field of using artificial intelligence in healthcare.

As a part of the study, we used different research methods including comparative legal research. The use of a comparative approach helped to define the reasons for choosing this approach and identify the benefits of comparing laws from different jurisdictions or time periods, such as finding common ground or determining best practices and solutions. The comparative method helped to better understand our home jurisdiction by analyzing how other jurisdictions handle the same issue. This method can also be used as a critical analytical tool to distinguish particular features of law. The drawback of this method is that it can be difficult to find material from other jurisdictions.

Discussion

Technologies based on AI are now used in health services in countries of the Organization for Economic Co-operation and Development (OECD), and its utility is being assessed in

low- and middle-income countries (LMIC). The United Nations Secretary-General has stated that the safe deployment of new technologies, including AI, can help the world to achieve the United Nations Sustainable Development Goals (1), which would include the health-related objectives under Sustainable Development Goal. AI could also help to meet global commitments to achieve universal health coverage.

The use of AI for health nevertheless raises trans-national ethical, legal, commercial, and social concerns. Many of these concerns are not unique to AI. The use of software and computing in health care has challenged developers, governments and providers for half a century, and AI poses additional, novel ethical challenges that extend beyond the purview of traditional regulators and participants in health-care systems. These ethical challenges must be adequately addressed if AI is to be widely used to improve human health, to preserve human autonomy and to ensure equitable access to such technologies. Use of AI technologies for health holds great promise and has already contributed to important advances in fields such as drug discovery, genomics, radiology, pathology, and prevention. AI could assist healthcare providers in avoiding errors and allow clinicians to focus on providing care and solving complex cases. The potential benefits of these technologies and the economic and commercial potential of AI for health care presage ever-greater use of AI worldwide.

The Universal Declaration of Human Rights, which includes pillars of patient rights such as dignity, privacy, confidentiality, and informed consent, might be dramatically redefined or undermined as digital technologies take hold and expand. The performance of AI depends (among other factors) on the nature, type, and volume of data and associated information and the conditions under which such data were gathered. The pursuit of data, whether by the government or companies, could undermine privacy and autonomy at the service of a government or private surveillance or commercial profit. If privacy and autonomy are not assured, the resulting limitation of the ability to exercise the

full range of human rights, including civil and political rights (such as freedom of movement and expression) and social and economic rights (such as access to health care and education), might have a wider impact [1].

Machine learning algorithms can learn to see samples the same way doctors see them. The key difference is that algorithms require many concrete examples - many thousands - to learn. And these examples need to be carefully digitized - machines cannot read between the lines in textbooks.

Thus, machine learning is especially useful in areas where the diagnostic information that the doctor is researching has already been digitized. Such as: Detecting lung cancer or stroke based on computed tomography, assessing the risk of sudden cardiac death or other heart disease based on electrocardiograms and MRI images of the heart, classifying skin lesions on skin images, detecting indicators of diabetic retinopathy on images of the eyes.

According to the German Medical Device Act (Medizinproduktegesetz - MPG) as well as the upcoming European Medical Device Regulations (MDR), the intended purpose of the software is critical. Broadly speaking, this means that if the software is designed to detect or treat disease, there is a strong case for classifying it as a medical device - for example, if it helps diagnose, facilitates therapeutic decisions, or calculates the dosage of medication. On the other hand, if software only provides knowledge or only stores data, it cannot be considered a medical device. However, the manufacturer defines the intended use, so there is some leeway based on the functional design of the application [2].

As the public health coordinating body for the United Nations system WHO is uniquely positioned to provide guidance, build capacity, shape the research agenda and engage stakeholders in improving the ethical framework for the use of big data and AI in public health. Developing global ethical guidance for the Member States also requires an analysis of knowledge gaps and the identification of research priorities to fill those gaps.

From 2 to 4 October 2019, WHO hosted an international consultation involving government,

intergovernmental agencies, academia, civil society and industry to begin developing WHO ethics and policy guidance for the development and implementation of AI in global health. Participants, including technologists, lawyers, medical practitioners, scientists, and ethicists, were selected from different WHO regions and shared their experiences with regard to the current and intended use of artificial intelligence technologies for public health, as well as ethical considerations and human rights principles. which should be guided when using it. Experts discussed various use cases for AI, such as in drug discovery, clinical medicine, and public health, and how it is changing these areas. They have heard of various related initiatives led by international organizations and governments. Finally, they discussed the relevant ethical issues that arise from these use cases and provide guidance on the format and content elements to be included in future guidance developed by WHO during additional consultations planned for 2020.

At the end of June 2021, WHO pointed to the negative consequences of the use of artificial intelligence in medicine, if its development, deployment, and use are not based on ethical principles and the protection of human rights.

Like all new technologies, artificial intelligence can be misused and harm patients said WHO Director-General Tedros Adhanom Ghebreyesus. To regulate and monitor the use of AI in medicine, WHO has published new guidelines that set out six principles for limiting risks and maximizing AI's health benefits [3].

The WHO report, *The Ethical Principles, and Applications of AI for Healthcare* indicates that AI can be used to accelerate and improve the accuracy of diagnosis and screening of diseases, help in complex clinical situations, accelerate health research and drug development, and support various public health measures, including outbreak response and health systems management. Artificial intelligence also allows patients to self-track their own health status and enables countries with limited resources to access health services remotely.

However, experts caution doctors and patients against overly enthusiastic assessments

of the health benefits of AI. WHO points out the possibility of unethical collection and use of health data, the manifestation of various biases of human communities in AI algorithms, and also recalls the risks related to patient safety, cybersecurity and the environment. In addition, WHO notes that systems trained on data from high-income countries may be ineffective in low- and middle-income countries.

To date, the global COVID-19 pandemic has spurred not only medical scientists to create a vaccine, but also innovative technology scientists who are working on the development of a variety of tools using artificial intelligence to facilitate the work of doctors. For example, in order to improve the efficiency of diagnostic activities, the Chinese web service company Baidu has developed and implemented an AI-based body temperature measurement system that provides fast and convenient monitoring of temperature parameters. The system was quickly deployed at transport hubs, including train stations and metro stations, and has become one of the most effective ways to combat the epidemic.

The use of smart cameras in China and Taiwan has made it possible to identify people who are not wearing masks, as well as to conduct thermal scans of people's body temperature in real-time to detect possible infections. SenseTime, an artificial intelligence technology company, announced that its non-contact temperature detection software has been installed in subway stations, schools, and community centers in Beijing, Shanghai, and Shenzhen. In turn, the retail giant Alibaba has proposed a new artificial intelligence-based coronavirus diagnostic system. The system detects new cases of coronavirus with an accuracy of 96%. For these purposes, computer tomographs are used, which record all the parameters of the human body and conduct a quick analysis of the data [4].

Last summer, the State Council of China released the Next Generation Artificial Intelligence Plan («Plan»), which sets the goal of making China a global leader in AI by 2030. In the Plan, China's AI goals are divided into three "Strategic Objectives" to be met by 2020, 2025, and 2030, respectively. By 2020, the plan aims to

bring China's AI in line with global standards, with major advances in AI applications and theory, and a «mainstream AI industry» worth at least 150 billion yuan. By 2025, it aims to begin developing AI laws and regulations, as well as creating a core AI industry with a production volume of at least 400 billion yuan, including sectors such as smart manufacturing, medicine, agriculture, and urban planning. Finally, by 2030, the Plan aims to make China the world's leading AI developer, with AI deeply embedded in everyday life and a core industry exceeding one trillion yuan.

To achieve these quantitative goals, the Plan lays out a number of «target objectives» that relate to the use of AI to solve social, economic, and national security problems. The Plan also lays out several "safeguards" to support and guide the development and use of AI, such as the necessary laws and regulations, ethical frameworks, and resource allocation principles. While the Plan lacks specific details, its ambitious agenda and selected policy targets indicate important sectoral, legal, and regulatory changes in the near future.

Based on the plan of the State Council of the USA, on December 13, 2017, the Ministry of Industry and Information Technology (MIIT) published the "Three-Year Action Plan to Promote the Development of the Next Generation of the Artificial Intelligence Industry (2018-2020). «(«Action Plan») The Action Plan encourages efforts in key areas including autonomous vehicles, intelligent service robots, intelligent drones, medical imaging diagnostic assistance systems, video, and image identification systems, intelligent voice interactive systems, intelligent systems translation and smart home products. It also calls for breakthroughs in "core fundamental" technologies, including smart sensors, neural network chips, and open-source platforms. Finally, the Action Plan calls on the government and the financial industry to support AI initiatives [5].

The innovator Graphen is working with Columbia University to determine the canonical form of localization of each gene of the virus and to determine the exact pattern. The company uses

its Ardi AI platform, which mimics the functions of the human brain, to store and visualize virus mutation data. The virus is displayed as a red dot during imaging. The green dot is a set of viruses with the same genome sequence. By clicking on the red dot, scientists can see all the information about the virus, including the location of the infected people, their gender, and their age [6].

The European Commission adopted its AI strategy for Europe in April 2018. In this communication, the Commission launched a European Initiative on Artificial Intelligence, which aims, *inter alia*, to ensure an appropriate ethical and legal framework, for example, through the creation of the European AI Alliance and the development of guidelines for AI ethics. The Commission also emphasizes in this Communication that the entire European Union (EU) should aim to increase (public and private) investment in AI to at least € 20 billion by the end of 2020.

Subparagraph a) 22 of clause IV of chapter IV of the Decree of the President of the Russian Federation of October 10, 2019 N 490 «On the development of artificial intelligence in the Russian Federation» states that the use of artificial intelligence technologies in the social sphere contributes to the creation of conditions for improving the living standards of the population, including by improving the quality of healthcare services (including preventive examinations, diagnostics based on image analysis, predicting the onset and development of diseases, selecting optimal dosages of drugs, reducing the threat of pandemics, automation, and accuracy of surgical interventions) [7].

Results

Based on the results of our research, it can be concluded that today there is no universal document regulating AI, not only in the field of medicine but also generalized and applied in all spheres of life. In addition, it can be noted that all documents of international organizations and medical associations regarding the use of AI in healthcare are of a recommendatory nature and

cannot be applied in a comprehensive form in all medical and legal cases.

The studies made it clear that the international legal regulation of the use of AI in medicine is still in the process of its formation. In this regard, it will be advisable, to regulate legal issues at the national and regional levels, in order to further combine and analyze research done in different parts of the world, in particular, guided by the experience of countries developed in terms of AI, to create a universal international legal document.

Governments should support the global governance of AI for health to ensure that the development and diffusion of AI technologies are in accordance with the full spectrum of ethical norms, human rights protection, and legal obligations.

Global health bodies such as WHO, Gavi, the Vaccines Alliance, the Global Fund to Fight AIDS, Tuberculosis and Malaria, Unitaid, and major foundations should commit themselves to ensuring that adherence to human rights obligations, legal safeguards, and ethical standards is a core obligation of all strategies and guidance.

International agencies, such as the Council of Europe, OECD, UNESCO and WHO, should develop a common plan to address the ethical challenges and the opportunities of using AI for health, for example through the United Nations Interagency Committee on Bioethics. The plan should include providing coherent legal and technical support to governments to comply with international ethical guidelines, human rights obligations, and the guiding principles established in this report.

Conclusion

The potential of AI in healthcare is enormous. Continuous progress in digitization ensures that AI-powered applications are increasingly used in everyday work. From the outset, those actively involved in this area must take into account not only technical aspects but especially legal issues. Thus, it will be possible to analyze, assess and mitigate legal risks. Perhaps an app that uses

legal technology could help with this, as it is well known that artificial intelligence is gaining momentum in the legal world as well.

For AI to be successful, healthcare leaders, physicians, and developers need to recognize that AI healthcare is not only a technical issue but also an ethical, legal and social issue. Research shows that the public is ready to support the use

of medical data for technological development but subject to strict confidentiality, proper control and management, and guaranteed use of data in the public interest.

Investments are needed in technologies to reduce the identity of data that protect patient privacy while encouraging the use and sharing of data.

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Денсаулық сақтау саласында жасанды интеллекті қолданудың халықаралық құқықтық реттелуі

Аңдатпа. Денсаулық сақтау саласында жасанды интеллект технологияларын қолдану шынымен де әсерлі перспективалар ұсынады. Сонымен қатар, денсаулық сақтау саласы дәстүрлі және ақылға қонымды. Дәрілік заттардан инновациялық шешімдерге дейін белгілі бір технологиялар мен өнімдерді қолданудың көптеген мәселелері құқықтық реттеу арқылы мемлекеттік бақылау мен басқаруға жатады. Бұл мақалада біз ЖИ-ті денсаулық сақтау саласында қолдануды реттейтін кейбір маңызды нормативтік құқықтық актілерді (НҚА) тізбеледік. Мақалада халықаралық деңгейде де, ұлттық деңгейде де денсаулық саласында жасанды интеллекті қолдануға қатысты халықаралық құқықтық нормалар талданады. Шолу жасанды интеллекті медицинаның әр түрлі салаларында, мысалы, ауруларды диагностикалау, оларды емдеуге ұсыныстар және денсаулық сақтау саласындағы әкімшілік іс -әрекеттерді қолдану мәселелерін зерттейді. ЖИ даму перспективалары, қарама -қайшы көзқарастар мен оны жүзеге асырудағы ықтимал тұзақтар талданады.

Кілт сөздер: жасанды интеллект, машиналық оқыту, денсаулық сақтау, адам құқықтары, құқықтық реттеу, ДДҮ.

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Международно-правовое регулирование использования искусственного интеллекта в сфере здравоохранения

Аннотация. Использование технологий искусственного интеллекта в здравоохранении открывает поистине впечатляющие перспективы. В то же время отрасль здравоохранения традиционно и достаточно консервативна. Многие вопросы применения определенных технологий и продуктов, от лекарств до инновационных решений, подлежат государственному контролю и управлению посредством правового регулирования. В этой статье мы перечислили некоторые важные нормативные правовые акты (НПА), которые так или иначе регулируют использование ИИ в здравоохранении. В статье анализируются международно-правовые нормы использования искусственного интеллекта в области здравоохранения как на международном, так и на национальном уровнях. В статье рассматриваются проблемы использования искусственного интеллекта в различных областях медицины, таких как диагностика заболеваний, рекомендации по их лечению, административная деятельность в сфере здравоохранения. Анализируются перспективы развития ИИ, противоречивые взгляды и возможные подводные камни при его реализации.

Ключевые слова: искусственный интеллект, машинное обучение, здравоохранение, права человека, правовое регулирование, ВОЗ.

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