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ARTIFICIAL INTELLIGENCE IN HEALTH CARE - APPLICATIONS, POSSIBLE LEGAL IMPLICATIONS AND CHALLENGES OF REGULATION***

Recent developments in the application of artificial intelligence (AI) in health care promise to solve many of the existing global problems in improving human health care and managing global legal challenges. In addition to machine learning techniques, artificial intelligence is currently being applied in health care in other forms, such as robotic systems. However, the artificial intelligence currently used in health care is not fully autonomous, given that health care professionals make the final decision. Therefore, the most prevalent legal issues relating to the application of artificial intelligence are patient safety, impact on patient-physician relationship, physician's responsibility, the right to privacy, data protection, intellectual property protection, lack of proper regulation, algorithmic transparency and governance of artificial intelligence empowered health care. Hence, the aim of this research is to point out the possible legal consequences and challenges of regulation and control in the application of artificial intelligence in health care. The results of this paper confirm the potential of artificial intelligence to noticeably improve patient care and advance medical research, but the shortcomings of its implementation relate to a complex legal and ethical issue that remains to be resolved. In this regard, it is necessary to achieve a broad social consensus regarding the application of artificial intelligence in health care, and adopt legal frameworks that determine the conditions for its application.

Keywords: artificial intelligence (AI), health care, legal implications, regulation, protection.

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1. INTRODUCTION

Humanity is on the way to a fully technological, data-driven, digital world of health care, with new possibilities for diagnosing and treating diseases, as well as medicines that should contribute to a longer and healthier life. Clinicians, geneticists and technobiologists agree that the path to a healthier and longer life leads through personalized digital medicine, with therapies tailored to the individual, based on the analysis of his/her hereditary material and other individual data. The medical, digital and technical progress of humanity will be further enhanced by the increasingly widespread utilisation of artificial intelligence technology.

Nowadays the main problems of health care systems in many countries around the world are cost, quality and access to health care (Sovilj, 2018, pp. 143-161). The aim of healthcare is to become more personal, preventive, predictive and participatory (Sjeničić, 2011, p. 425). In an effort to improve and advance the health care system, scientists have begun to develop innovative technology like artificial intelligence, which will contribute to the achievement of those objectives. From a review of the progress made, we estimate that artificial intelligence will continue its impulse to evolve and mature as a powerful tool in health care (Rong *et al.*, 2020, p. 292).

Having in mind that artificial intelligence aims to imitate human cognitive functions, it is bringing a paradigm change to health care, powered by the increasing availability of healthcare data and immediate progress of analytics techniques. Artificial intelligence can be applied to different types of healthcare data. Accepted artificial intelligence techniques involve “machine learning methods for structured data, like the classical support vector machine and neural network, and the modern deep learning, as well as natural language processing for unstructured data” (Jiang *et al.*, 2017, p. 230). In a health care system, the artificial intelligence can be used to enhance the efficiency and quality of patient’s life, as well as improving medical research. Until now, roughly 86% of health care providers (professionals) use at least one form of artificial intelligence in their practices (Kamensky, 2020, p. 1).

Namely, the legal issues that humanity is already facing due to the use of artificial intelligence in health care refer to, *inter alia*, patient safety, impact on patient-physician relationship, physician’s responsibility, the right to privacy, data protection, intellectual property protection, and lack of proper regulation. The objective of this research is to comprehend the advantages of technologies, to appreciate the vast potential of artificial intelligence in health care and to point out certain controversial legal issues that humanity will face in the foreseeable future with the increasing prevalence of artificial intelligence in health care. Hence, the aim of this paper is to rationally understand the possibility of endowing artificial intelligence with a status of legal personality and to reveal the problems associated with legal regulation in health care system, in which artificial intelligence is used. Therefore, we will primarily analyze the issue of the legal nature of artificial intelligence, while the remainder of this paper will be devoted to the legal consequences of the applications of artificial intelligence in health care, as well as the challenges faced by regulatory bodies in the regulation of artificial intelligence.

2. THEORETICAL CONCEPT AND LEGAL NATURE OF ARTIFICIAL INTELLIGENCE

Artificial intelligence has been discussed in scientific literature since the 1940s, when mathematician John Von Neumann devised the stored-program computer architecture - the idea that a computer's program and the data it processes can be stored in a computer's memory. In 1943, Warren McCulloch and Walter Pitts laid the foundations for the development of neural networks, i.e. architecture of neural network for creating intelligence (Prlja, Gasmi & Korać, 2021, p. 57). It is generally accepted that the modern field of artificial intelligence begins in 1956 during a conference at Dartmouth College, held under cover of the Defense Advanced Research Projects Agency (DARPA) (Prlja, Gasmi & Korać, 2021, p. 58). During this conference, John McCarthy first used the term artificial intelligence, when he determined intelligence as the computational part of the ability to achieve objectives in the world. According to McCarthy, intelligence includes mechanisms, and artificial intelligence has discovered how to make computers carry out some of them and not others (McCarthy, 2007, pp. 2-3). Therefore, with artificial intelligence, it is about computer systems being developed to such a level that they can independently perform functions that are traditionally performed exclusively by humans. Similar to people, there are new information systems that are capable of learning independently and undertaking different activities. Nowadays, the term artificial intelligence mainly refers to systems based on machine learning and deep learning, as well as other systems (Milosavljević, 2023, p. 500).

Artificial intelligence could be seen as a branch of the economy, an independent scientific discipline, or an area within computer science. Additionally, artificial intelligence could be seen as a new level of development of information and communication technologies (Andonović, 2020, p. 113). If we consider AI as an economic branch, artificial intelligence represents one of the richest markets in the world. The global artificial intelligence market size was valued at \$136.55 billion in 2022 and is designed to extend at a compound annual growth rate (CAGR) of 37.3% from 2023 to 2030. The permanent research and innovation conducted by tech giants are driving the adoption of advanced technologies in many branches, such as health care, finance, retail, manufacturing, and automotive. *Exempli gratia*, from crucial life-saving medical devices to self-driving vehicles and unmanned aerial vehicles (drones), artificial intelligence is being infiltrated virtually into every machine and program (Grand View Research, 2023).

Artificial intelligence could be seen, also, as a scientific discipline or as a branch of Computer Science. If we determine artificial intelligence as a scientific discipline, the primary subject of its research is focused on automation, i.e. digitalization of the intelligent behavior of machines and programs. This behavior can relate to different forms of existence - from people, animal world, vegetation, and even objects (Chowdhary, 2020, p. 1).

If we consider artificial intelligence as a work tool, then it is used as a method of replacing the use of human intelligence in certain situations. Artificial intelligence can be viewed as ability of a computer or other machine to execute actions thought to require intelligence. Among these actions are logical deduction and conclusion, creativity,

the capability to make decisions based on past experience or incomplete or conflicting information, and the capability to understand spoken language (Andonović, 2020, p. 113). According to Chowdhary, the fundamental materials of artificial intelligence constitutes: „data structures, knowledge representation techniques, algorithms to apply the knowledge and language, and the programming techniques to implement all these“ (Chowdhary, 2020, p. 2).

For numerous scientists and researchers, the aim of artificial intelligence is to imitate human cognition, while to certain scientists, AI is the formation of intelligence without considering any human features. On the other side, according to some scientists, the aim of artificial intelligence is to create useful items for the convenience and needs of human, without any criteria of an abstract notion of intelligence (Chowdhary, 2020, p. 4).

However, in the scientific literature a convincing argument is that due to the absence of an acceptable definition of artificial intelligence, it is difficult to determine the legal nature of AI. Can artificial intelligence be subsumed under existing legal categories, or is it a *sui generis* category that needs to be developed and legally formalized? One of the legal standpoints observes artificial intelligence as a general property because AI is creating intelligence in machines and programs, and not necessarily based on any characteristics of humans (Chowdhary, 2020, p. 4). However, from the perspective of copyright law, artificial intelligence cannot be recognized as an author based on the different cases related to animals, especially the famous case of the monkey's selfie.

In addition, a major dilemma in the legal theory and practice is about providing artificial intelligence with legal personality (subjectivity), particularly on the grounds of civil law. Legal personality, and the ability to be the holder of rights and obligations and to determine one's own legal situation, is prescribed by the law to human beings (natural persons) (Krainska, 2018). A human being has intelligence, feelings, free will, and self-awareness. How then should the law answer the question whether an artificial intelligence can acquire a legal personality, when it has not feelings, free will, and self-awareness? (Solum, 1992, p. 1243). Considering that legal personality is a compound institute, it can be recognized to certain entities or assigned to others. Hence, the notion of legal personality in the sense of the ability to be the holder of rights and obligations and to establish one's own legal situation has been extended to cover entities grouping together individuals sharing common interests, such as states or commercial entities (e.g. corporations). They are "artificial" creations, known as legal persons, designed by the humans standing behind them (Krainska, 2018).

Almost all legal scholars and practitioners agree that legal personality in the form recognized to a human being is unique and cannot be recognized to artificial intelligence because, at least for now, artificial intelligence does not indicate any evidence of being conscious and sentient (Wojtczak, 2022, p. 206). In the legal theory, when discussing the opportunity of recognition legal personality to artificial intelligence, two standpoints are represented. On the one side, artificial intelligence is compared to animals by analogy, while on the other side, artificial intelligence is compared to legal persons or collective entities (e.g. states, municipalities, companies, and associations). A *contrary*, analogy with animals seems more acceptable, as the capability of artificial

intelligence is limited in regard to humans. Also, artificial intelligence can be like collective entity in the sense that it is an artificial creation, a non biological one lacking in sensations and awareness (Wojtczak, 2022, p. 207). If we assume that in the future artificial intelligence would develop to such an extent that it could achieve complete reason, or a form superior than human reasoning, and if it gained some feeling, it would be upraised above collective entities and classified on par with humans. In that case, the advocates of this view believe that artificial intelligence cannot acquire dissimilar legal personality to that enjoyed by animals or collective entities, it must be analogous, derivative (Wojtczak, 2022, p. 207).

The issue of legal personality for artificial intelligence undoubtedly indicates that even if its ascription resolves some problems, it will induce others. Many legal scholars and practitioners warn that such ascription would not enable those who develop and employ artificial intelligence to outsource and avoid liability, thus incentivizing them to take risks and externalise costs because they know they will not be responsible (Hildebrandt, 2019, p. 12).

In the legal literature, there are some authors who advocate for the recognition of legal personality to artificial intelligence, but without any responsibility, which is *contradictio in adjecto*. Therefore, the determination of the legal personality of artificial intelligence must be approached carefully, considering that the recognition of legal personality entails certain rights and obligations, of which, at least for now, artificial intelligence has not consciousness. For instance, for a robot equipped with artificial intelligence, it is hard to say that it has a free will which can lead to commission of prohibited acts with the goal of achieving its own ends. Thus, a degree of fault, such as negligence or recklessness cannot be ascribed to it. Nor is it possible to hold it responsible for damage it caused, *exempli gratia*, such as malpractice by surgical robots or in the case of an accidents caused by an autonomous vehicles or drones (Krajska, 2018). The reason is based on the assumption that an artificial intelligence could not be responsible, that is, it could not compensate for damages, or be punished in the event that it breached one of its duties, because AI is not aware of its obligations.

If we look only at the utilization of artificial intelligence in health care, it is necessary to establish the fundamental legal problems and challenges in the application of artificial intelligence, such as: 1) data protection and the right to privacy; 2) responsibilities; 3) intellectual property protection; 4) security, efficiency and transparency and 5) cyber security (Sovilj, 2023, p. 17).

3. THE APPLICATION OF ARTIFICIAL INTELLIGENCE IN HEALTH CARE – LEGAL IMPLICATIONS

As in other branches, health care is characterized by a rapid increase in data and sophisticated artificial intelligence tools that could be used to find complex patterns in that data. In health care, data come from numerous sources: electronic health records (e-records), medical literature, clinical trials, health insurance claims data, pharmacy records, even information that patients enter into certain apps on their smartphones. On

the ground of collected numerous data and using sophisticated machine learning techniques, scientists have developed applications to improve the efficiency and quality of patients care, as well as to advance medical researches. The aforementioned tools rely on algorithms, i.e. programs created on the basis of health data, which can provide predictions or recommendations (Sovilj, 2023, p. 15).

Nowadays, artificial intelligence tools are used, *inter alia*, in radiology (screening and diagnosis), the accuracy of ultrasound diagnosis, patient counselling support by predictive algorithms, artificial reproduction technologies, pregnancy risk monitoring (prenatal diagnosis, hypertension disorders in pregnancy, foetal growth, gestational diabetes, preterm deliveries) (Silva Roch *et al.*, 2022, p. 2). Artificial intelligence tools are also being used to detect lung changes caused by the COVID-19 virus. AI acts preventively and provides us with advance warnings about various diseases, stress and even dementia (Prlja, Gasmi & Korać, 2022, p. 44).

In addition to machine learning techniques, artificial intelligence is currently applied in medicine in other forms, such as robotic systems. Among the most widespread robotic systems used in health care is the da Vinci Surgical System. Since 2000, when the American Food and Drug Administration (FDA) authorized its use, more than 7 million surgical procedures have been performed around the world using da Vinci Surgical System. In the previous period, there was growing interest in the development of so-called social robots in health care. The most famous examples of them are: ASIMO by Honda, AIBO by Sony, PARO by Japan's National Institute of Advanced Industrial Science and Technology, Kaspar by University of Hertfordshire, Pepper from SoftBank Robotics and others (Wojtczak, 2022, p. 211). Additionally, health care institutions and nursing homes in Japan particularly utilize exoskeletons and exomuscles which help elderly patients to perform daily activities. Aiming at lessening the strain on physical therapists to train patients with serious or degenerative disabilities, motor cognitive limitation and at improving their quality of life, exoskeletons are applied in the field of rehabilitation, mainly on patient training (Guan, Ji & Wang, 2016, p. 1). Therapeutic Robot PARO, the so-called seal robot, is used in more than 30 countries in the world. Over 80% of state-run nursing homes in Denmark use the seal robot. In addition to the treatment of elderly people, robots are used in communication with children who stay in hospital for a long time, to hold psychotherapeutic sessions, lectures to students, etc.

Among recent examples of social robots in healthcare, global pharmaceutical company Merck teamed up with Furhat Robotics to reshape the way medical professionals approach early detection and diagnosis of common diseases. Merck has developed PETRA, a social robot that has the capability to detect signs of the three of the world's most common, yet under-diagnosed diseases: alcoholism, diabetes, and hypothyroidism (Furhat robotics, 2020). Also, the recent pandemic has emerged as an opportunity for artificial intelligence to enable computer systems to fight against the outbreaks, as several tech giants and start-ups commenced working on preventing, mitigating, and containing the virus.¹

¹ For instance, the Chinese tech giant Alibaba's research institute Damo Academy has developed a diagnostic algorithm to detect new coronavirus cases with the chest CT (Computed Tomography) scan. The

However, the artificial intelligence used in health care is not fully autonomous in contrast to the artificial intelligence technology used in autonomous vehicles or unmanned aerial vehicles. Namely, the current application of artificial intelligence in health care is characterized as a technology that helps health care professionals to make decisions based on previously provided information or analysis (big data), while the final decision is taken by health care providers. “Even insisting that artificial intelligence has no decision-making potential, but that a person has power over it and that the artificial intelligence only provides a basis for human decisions, i.e., the result of reasoning, it cannot be denied that an artificial intelligence that communicates with a health care professional through an understandable language has the capability to influence the decisions of health care professionals” (Wojtczak, 2022, p. 211). In this regard, the issue is whether health care professionals should be fully responsible for the decisions proposed or made by artificial intelligence algorithms, bearing in mind that the use of artificial intelligence can create unpredictable risks. Therefore, it is disputed and legally uncertain whether the traditional institutes of legal responsibility can be applied to medical errors, made on the ground of artificial intelligence decisions (Sovilj, 2023, p. 16). The majority of medico-legal standards are also undetermined as to where the limits of liability begin or end when artificial intelligence agents guide clinical care.

Namely, the legal problems that society is already facing due to the use of artificial intelligence in health care relate to the privacy concerns with the data used for training artificial intelligence models, and safety and responsibility issues with artificial intelligence application in clinical environments, surveillance, bias, and discrimination (Reddy *et al.*, 2020, p. 491). Despite promising and encouraging results in the diagnosis and treatment of diseases, decisions made under the influence of AI bias can lead to discrimination against patients (even before they are born) and unintentional harm. Human biases transferred to the artificial intelligence algorithms can produce discrimination of future patients based on ethnicity, race, citizenship status, marital status, sexual orientation, gender, religion, and political orientation. Biased algorithms can lead to an underestimation or overestimation of risk in specific patient populations (Reddy *et al.*, 2020, p. 492). In this regard, artificial intelligence technology represents a dangerous instrument of abuse. The misuse of artificial intelligence raises concern due to its possibility to become a new source of negligence, inaccuracies, and violations of patients’ rights. In the absence of appropriate legal regulation, accelerated progress in development and application of artificial intelligence could lead to insecure and morally flawed practices in health care. In a high-risk profession such as health care, errors caused by the use of artificial intelligence can have fatal consequences for patients (Sovilj, 2023, p. 16). Therefore, a more detailed and comprehensive legal approach is necessary in regulating the use of artificial intelligence in health care.

artificial intelligence model used in the system has been trained with sample data from over 5,000 positive coronavirus cases. In June 2020, *Lunit* developed an artificial intelligence solution for the X-ray analysis of the chest for simpler management of COVID-19 cases and offered assistance in interpreting, monitoring, and patient trials (Grand View Research, 2023).

4. CHALLENGES OF REGULATION OF ARTIFICIAL INTELLIGENCE IN HEALTH CARE

Legal and normative standards for the application of artificial intelligence in health care should be primarily developed by governmental bodies, regulatory authorities, and health care institutions. Legal standards should promote how artificial intelligence will be created and applied in the context of health care and should be consistent with the fundamental principle of law, namely justice. The principle of justice includes equity in access to health care. Consequently, the application of artificial intelligence should not lead to discrimination, or health inequities. “The legal framework should provide procedural (fair process) and distributive justice (fair allocation of resources) to be respected, in order to protect against hostile attack or the introduction of biases or errors through self-learning or malicious intent” (Reddy *et al.*, 2020, p. 493). Hence, the artificial intelligence applications need to be reviewed for their data protection, transparency, and bias minimization characteristics in addition to safety and quality risks and protections against malicious attack or unintentional mistakes.

Currently, there is no legislation in the world that specifically regulates the use of artificial intelligence in health care. As aforementioned, for the approval of artificial intelligence applications, which covers license for the marketing and utilize of AI in health care, governmental bodies and regulatory authorities have a crucial role. For instance, in the USA, the Food and Drug Administration (FDA), which regulates medicines and medical devices, has introduced steps to approve software for medical use (Reddy *et al.*, 2020, p. 495). In July 2016, the FDA issued three guidelines meant to encourage medical entrepreneurs to deploy and use devices that rely on advances in artificial intelligence in health care. In response to the growth of the digitalization of health care, through the use of artificial intelligence, the FDA is focused on creating a digital health unit within its Center for Devices and Radiological Health (CDRH) to include time and resources to invest in artificial intelligence (Bailey-Wheaton, 2017, p. 1). The CDRH facilitates “medical device innovation by advancing regulatory science, providing industry with predictable, efficient, consistent, and transparent regulatory pathways, and assuring consumer confidence in devices marketed in the USA” (Bailey-Wheaton, 2017, p. 1).

In the United Kingdom, the use of artificial intelligence is regulated by a patchwork of more general legislation, such as the Data Protection Act 2018, or the Medical Devices Act 2021, covering certain applications of artificial intelligence in health care. In June 2022, the Medicines and Healthcare products Regulatory Agency (MHRA) adopted guideline entitled Government response to consultation on the future regulation of medical devices in the United Kingdom. The MHRA outlined that “artificial intelligence as a medical device (AIaMD) would be treated as a subset of software as a medical device (SaMD)”, which means that a robust guidance will be provided, but it will not be separated from the guidance for software (MHRA, 2022, pp. 121-123). The guidance, in addition to secondary legislation, will structure the legal framework in the UK. As opposed to legislation, one of the advantages of guidance is that it allows for a flexible and reactive approach to change (Vollers & Dennis, 2023).

At the EU level, in 2021, a proposal for a Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) was adopted. It was the first comprehensive law which regulates artificial intelligence. This proposal constitutes a core part of the EU digital single market strategy (Raposo, 2023, p. 2). The main objective of this proposal is “to provide the proper functioning of the internal market by setting harmonised rules in particular on the development, placing on the Union market and the utilize of products and services making use of artificial intelligence technologies or provided as stand-alone AI systems”. Meanwhile, some EU member States are considering national rules to make sure that artificial intelligence technologies are safe and are developed and used in compliance with fundamental rights obligations (Proposal of AI Act, 2021, p. 6).

In June 2023, the European Parliament has adopted an Artificial Intelligence Act that comes into force a short time after being published in the *Official Journal of the European Union*. The exact timeline is still being debated, but various parts of this Act will commence being implemented at different times, approximately during the first 2-3 years after the act comes into force. The main objective of this legislation is to create a more or less uniform legal framework across all EU Member States in relation to the use of artificial intelligence (Schneeberger, Stoger & Holzinger, 2020, p. 212).

The Artificial Intelligence Act uses a risk-based approach. The AI Act categorises artificial intelligence systems based on levels of risk as: unacceptable risk, high-risk, limited risk, and minimal or no risk. The level of unacceptable risk means that the artificial intelligence system must be deemed “a clear threat to the safety, livelihoods and rights of people”, and will be banned. For instance, this includes a complete ban on “the use of social scoring systems by public authorities and various uses of real-time remote biometric identification in public spaces” (Vollers & Dennis, 2023). In contrast to AI Act, the use of the social scoring system is approved by the government of the People’s Republic of China.

High-risk applications, such as a CV-scanning tool that ranks job applicants, are subject to additional legal requirements. In a health care system, for example, these tools could include robot-assisted surgery, medical devices with artificial intelligence, or *in vitro* diagnostic medical devices. Compliance assessments will be required for high-risk artificial intelligence systems. These tools will only be permitted to be placed on the EU if specified conditions are met, such as establishing a risk management system, complying with data governance requirements, and drawing up technical documentation (Vollers & Dennis, 2023). Current regulations, such as the Medical Device Regulation (Regulation (EU) 2017/745) and the *In Vitro* Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746) would still be applied. The Medical Device Regulation applies to software as medical devices, including AI-based software, while the *In Vitro* Diagnostic Medical Devices Regulation applies to *in vitro* based diagnostics, including AI-based. These regulations include new approaches for more rigid pre-market control, increased clinical investigation requirements, reinforced surveillance across the device’s lifecycle, and improved transparency by creating a European database of medical devices. However, many aspects specific to artificial intelligence are not taken into consideration,

such as continuous learning of the artificial intelligence models or the identification of algorithmic biases (EPRS, 2022, p. 30). In that case, the EU has an obligation to ensure that these regulations are harmonized and not inconsistent or contradictory.

Limited risk category systems will be subject to certain transparency obligations. In health care, for instance, these tools are artificial intelligence softwares that process data received from a fitness or heart rate monitors and provide results (Vollers & Dennis, 2023). At last, applications not explicitly prohibited or listed as high-risk are largely left unregulated.

5. CONCLUSION

As aforementioned, artificial intelligence is already helping to improve the quality and access to health care, and also has the potential to contribute to significant advances in health care. However, the use of artificial intelligence in health care represents a legal, ethical, social, and political challenge in the contemporary society. It is indisputable that artificial intelligence in health care must be safe, reliable, and effective. Nevertheless, the question is how to provide legal protection to health care professionals and patients while at the same time ensuring the unconstrained and efficient development and use of artificial intelligence technology in health care? One of the most significant challenges for the regulators and policymakers will be engendering confidence among health care professionals and trust in their use of artificial intelligence.

In order to achieve adequate legal protection in health care due to the use of artificial intelligence, its legal status needs to be defined. As we mentioned above, one of the main legal problem of defining the status of AI is of the theoretical nature, which is due to the objective inability to forecast all possible results of developing new models of artificial intelligence. Until now artificial intelligence has not possessed a legal personality and is considered objects of law. In the legal literature, there is no generally accepted standpoint regarding the legal personality of artificial intelligence. As we aforementioned, almost all legal scholars and practitioners agree that legal personality in the form recognized to a human being is unique and cannot be recognized to AI. Therefore, the determination of the legal personality of artificial intelligence must be approached carefully, considering that the recognition of legal personality entails certain rights and obligations, of which, at least for now, artificial intelligence has no consciousness.

The growing legal inconsistency is due to the accelerated development of artificial intelligence and its spreading in different sectors of health care. All this testifies to the increased risk of a break between legal matter and the changing social reality (Filipova & Koroteev, 2023, p. 360). This is the reason why a comprehensive regulation on the use of artificial intelligence in health care has not yet been adopted. Some of the rules such as guideline of MHRA or EU Regulations treated artificial intelligence as a subset of software as a medical device. In order to understand the vast potential of artificial intelligence in the transformation of health care in the future, it is necessary that all actors, from health care professionals and patients, to lawyers and ethicists, are involved in a public debate about the use and regulation of artificial intelligence. The aim of the

debate is to achieve a social consensus and set limits in determining the conditions for the use of artificial intelligence. Therefore, communication with the patients and health care professionals will be crucial to building trust and encouraging the use of artificial intelligence technology.

In this research we offer an overview of how the use of artificial intelligence can benefit future health care, in particular increasing the efficiency of health care professionals, and improving medical diagnosis and treatment. In that regard, legislation and guidelines should ensure ongoing assessment of artificial intelligence health care technologies, while acting as an enabler, realizing the enormous potential of technologies that could represent a huge leap forward over current treatment and diagnostic abilities for all patients (Vollers & Dennis, 2023). As artificial intelligence expands into new areas, a relevant legal framework will be one that can quickly and effectively deal with the rise of yet unfamiliar technologies. Only time will tell whether the envisaged regulatory framework will be sufficient to match the pace of artificial intelligence development.

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