Journal of Ethics and Legal Technologies – Volume 6(2) – December 2024

The use of artificial intelligence in healthcare and medicine - legal aspects[1]

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The advancement of technology in the last few decades has brought significant changes in various fields, especially in medicine and healthcare. The number of Artificial Intelligence-Based Healthcare Mobile Apps has grown significantly over the past few years. The application of AI in medicine and healthcare has, on one hand, brought numerous benefits, but on the other it has opened up different questions, primarily in terms of the safety of their application and liability. This also led to the question of whether the traditional way of legal regulation in the field of medicine and healthcare can be applied when it comes to new AI technologies and medical tools. The results of the research showed that it is necessary to change the existing legislation and/or adopt a new one. In the research we analysed new EU Artificial intelligence act and Serbian health regulations. The AI Act brought some significant changes. Based on the research that we conducted it can be concluded that the legal regulation does not keep pace with the changes brought by innovations, such as the application of AI in medicine and healthcare, but the legislation in this domain in Serbia lags behind.

Keywords: Artificial intelligence, healthcare, medicine, legislation

[1] This paper was written as part of the 2024 Research Program of the Institute of Social Sciences supported by the Ministry of Science, Technological Development and Innovation of the Republic of Serbia.

Artificial intelligence in healthcare and medicine

Since the term artificial intelligence was coined by McCarthy in the 1955 (McCorduck, 2004, 251) this field has changed significantly (see: Kulikowsk, 2019) leading to the possibility of using artificial intelligence (AI) in medicine and healthcare. Two main branches of application of AI in medicine and healthcare can be differentiated (Hamet, Tremblay, 2017, S37); virtual branch, which "includes informatics approaches from deep learning information management to control of health management systems, including electronic health records, and active guidance of physicians in their treatment decisions," and the physical branch "best represented by robots used to assist the elderly patient or the attending surgeon" (Hamet, Tremblay, 2017, S36).

Key role in Al technology's potential in the healthcare sector is the ability of Al to analyse a significant number of data sets (Delveinsight, 2023, 1). Literature lists several benefits of using medical diagnosis AI Apps: 1) Enhanced Accuracy and Speed; 2) Personalized Treatment Plans; 3) Early Detection and Prevention; 4) Optimized Resource Utilization; 5) Cost-Efficiency and Accessibility; 6) Continuous Learning and Adaptability; 7) Facilitation of Telemedicine; and, 8) Reduced Margin of Error (Technologically, 2024). The number of Artificial Intelligence-Based Healthcare Mobile Apps has grown significantly over the past few years (Delveinsight, 2023, 1).

Use of AI in medicine is widespread in the field of scheduling of appointments, digital health records, reminders for immunization, for follow-up appointments, etc. (Amisha et al., 2019, 2329). Most Al-based healthcare Apps can perform some of the basic functions that can free up clinicians' schedules. That can reduce "the burden on administrative departments, which helps healthcare organizations and physicians to interact more efficiently and effectively with patients and reduce the cost and time" (Delveinsight, 2023, 5). With AI-Based diagnosis apps, diagnosis can be better and faster informed by real-time data. Al-Based apps can reduce administrative errors and save important resources (Delveinsight, 2023, 5).

With the use of AI in analysing the clinical data, results of examinations in the field of radiology, ultrasonographic, endoscopic, biochemical examinations can be obtained faster (Liu et al., 2021, 1105). The role of AI in surgery is very significant. One of them is invention of da Vinci surgical system which enabled interventions with minimal invasion, making complex operations easier (Liu et al., 2021, 1107). Further on, IBM Watson for Oncology Harnessing cognitive computing analyses broad oncology literature and patient records to help oncologists to create personalized treatment plans. One more way to use AI in oncology is through Tempus: Precision Cancer Care.

AI is used to analyse clinical and molecular data which helps oncologists to make informed decisions for personalized cancer treatment (Technologically, 2024). Path AI uses AI to advance pathology diagnostics, enhancing the accuracy of disease identification in biopsy samples. By analysing patient data, DeepMind's AI algorithms predict acute kidney injury, thus assisting clinicians in early intervention and proactive care (Technologically, 2024). Zebra Medical Vision's algorithms use deep learning and digitized radiology scans (from X-rays, mammograms, and CT-scans) to assist doctors in making diagnoses (Greenstein, 2019, 1). AI can be also used in the field of dermatology. SkinVision is a medical service which can give greater control over the condition of the users' skin expanding the ability to self-examine and helping the user to know "when to act, how, and why" (Delveinsight, 2023, 3). Aysa is AI dermatology assistant. Anatomi is also using AI for dermatology by analysing skin images which can help with early detection of skin conditions aiding the dermatologists with diagnoses (Technologically, 2024). AI can also be helpful in the field of diabetes. IDx-DR uses AI for detecting diabetic retinopathy through analysis of retinal images, providing fast and accurate screening process. Insulin management plans for individuals with diabetes are tailored by DreaMed Diabetes using AI (Technologically, 2024). Virtual reality nursing assistant also exist. They "assists in checking the patient, record the vital results, then funnels them back to the physicians" (Delveinsight, 2023, 3). There are also AI-based healthcare apps for people who want to live healthy life. One of them is Noom which assesses weight, age, height, and aim of the user helping them in the weight loss process and in maintaining healthier lifestyle (Delveinsight, 2023, 2).

Considering that people's life expectancy is significantly longer and that the aging process brings with it numerous challenges, requiring for health care, in some cases long-term care (Stamenković 2022, 155; see: Sjeničić, Milenković, Nikolić Popadić, 2024), the use of AI for older can have a significant role. The *Survey on Health, Ageing and Retirement in Europe* from 2017, showed that on average 37% of people over 65 have at least two chronic diseases (OECD/European Union, 2020, 132), which puts a lot of pressure on health personnel which is already lacking in Europe (European Parliament, 2022, 20). The role of AI can be very important in "self-management of chronic diseases and diseases that affect the elderly" (European Parliament, 2022, 24). That can be help with taking medications, managing health devices, home monitoring, home service robot, mobile applications which can help patients in healthcare and their connection with healthcare system, etc (European Parliament, 2022, 12; see: Sapci & Sapci, 2019).

In addition to all the previously mentioned positive aspects of the use of AI, it is necessary to emphasize that Al still needs human supervision and has

informational and technical shortcomings, such as susceptibility to increasingly sophisticated cyber-attacks. With the increased application of AI in the healthcare sector "limitations and challenges must be tackled and overcome for a smooth user experience" and generation of trust (Delveinsight, 2023, 5).

The question is if personalised medicine, based on AI, is "old" or "new" medicine. This raises the question of whether the "old" law will be applied to this medicine, that is, conventional legal viewpoints, including the already established rights of patients, or whether a "new" legal system and "new" subjective rights of patients has to be developed.

Until now, the protection of the patient, through medical law, has focused on treatment, that is, on protecting the patient's life and health and ensuring his autonomy, in the form of the patient's right to self-determination. The right to treatment gives the patient the opportunity to seek protection against medical errors and possible liability due to negligence in treatment. The right to protection of self-determination gives the patient the opportunity to seek protection from arbitrary and insufficiently informed treatment and insufficient explanation (Sjeničić, 2011, 430).

Risks related to use of artificial intelligence in healthcare and medicine

There are different risks which can be associated with the use of AI in healthcare and medicine. Some studies identify several risks of AI in medicine and healthcare: "1) patient harm due to AI errors, 2) the misuse of medical AI tools, 3) bias in AI and the perpetuation of existing inequities, 4) lack of transparency, 5) privacy and security issues, 6) gaps in accountability, and 7) obstacles in implementation" (European Parliament, 2022, I). When it comes to *patient harm due to AI errors*, medical consequences of such errors may include "missed diagnosis of life-threatening conditions as well as false diagnosis, leading to inadequate treatment and incorrect scheduling or prioritisation of intervention" (European Parliament, 2022). Regarding *misuse of medical AI tools*, it can be caused by "limited involvement of clinicians and citizens in AI development, a lack of AI training in medical AI among healthcare professionals, lack of awareness and literacy among patients and the general public, and the proliferation of easily accessible online and mobile AI solutions without sufficient explanation and information" (European Parliament, 2022, II). *The most common causes of AI biases* in the healthcare sphere are due to "biased and imbalanced datasets which may be based on structural bias and discrimination and disparities in access to quality equipment and digital technologies, as well as lack of diversity and interdisciplinarity in

technological, scientific, clinical, and policymaking teams" (European Parliament, 2022). Some biases can be connected to the fact that certain subgroups of patients, like patients with rare diseases, may not exist in sufficient numbers for a predictive analytic algorithm. Therefore, clinical data retrieved from electronic health records might be prone to biases. Because of these potential biases, the accuracy of AI can be misleading when trained on a small subgroup or small sample size of patients with rare diseases (Choudhury & Asan, 2020, 3). Some of the specific risks associated with a *lack of transparency in biomedical AI* include a lack of trust and understanding in predictions and decisions made by the AI system, as well as difficulties in "independently reproducing and evaluating AI algorithms" (European Parliament, 2022, II). One of the problems may arise due to the fact that institutions record information about patients differently. Therefore, if AI models trained at one institution are implemented to analyse data at another institution, it might lead to potential errors. For example, machine-learning algorithms which are developed at a university hospital to predict patient-reported outcome measures are usually documented by patients with high education and high income. Those algorithms might not be applicable at a community hospital which primarily serves underrepresented law-income patients (Choudhury & Asan, 2020, 3). Different *risks for data privacy and security* are associated with use of AI for healthcare. Despite the fact that some risks, like security breaches of medical records, have existed for quite some time, their materialization in AI applications is likely to pose large-scale risks to privacy and confidentiality (Banja, 2020, 945). Some of the main risks are sharing personal data when fully informed consent is lacking, repurposing of data (when patient is not aware of it), exposure of sensitive or personal data/information, cyberattacks (European Parliament, 2022, II).

There are legal lacunae in the current national and international regulations "concerning who *should be held accountable or liable for errors or failures of AI systems, especially in medical AI"* (European Parliament, 2022, II). The multiplicity of actors who are involved in the process of medical AI (from design to deployment) makes it very difficult to define whose responsibility it is, healthcare professionals or AI developers. The lack of definition of roles and responsibilities can put healthcare professionals in hard and vulnerable position (European Parliament, 2022, III). The current system, due to severity of the consequences, requires someone to be held accountable for poor decisions. AI has been seen by many as a "black box", as researchers worry that it will be difficult to understand how an algorithm arrived at a certain conclusion. The question of accountability becomes much more important when considering AI applications that attempt to improve medical outcomes, especially when errors occur. Therefore, it is not clear who is to

blame in the event of a system failure. On the one hand, it might be difficult to pin the blame on the doctor when he/she was not involved in developing or overseeing the algorithm, while on the other hand, the developer's error might seem unrelated to the clinical setting (Khan et al., 2023, 5). Efforts to establish criteria for evaluating the security and efficacy of AI systems has been undertaken by the U.S. Food and Drug Administration (FDA), and National Health System is drafting standards for showing the effectiveness of AI-driven solutions. As those efforts are continuing it makes it more difficult for courts and regulatory agencies to accept AI-based actions. On the other hand, use of artificial intelligence for ethical decision-making in healthcare is prohibited in China and Hongkong (Khan et al., 2023, 3).

There are different obstacles on the way between development of AI medical tools and their use in practice, especially in the clinical practice. Some of them are limited quality of data, the question of possibility to exchange and use information and data across different clinics and e-health records, not completely regulated access to patients' data, change in relationship between physician and patient due to use of AI medical tools, the problem of integration of AI medical tools in existing clinical workflows, etc (European Parliament, 2022, III).

After providing risk assessment methodology, European Parliament recommend some policy options for overcoming the existing risks: 1) Extending AI regulatory frameworks and codes of practice to address healthcare-specific risks and requirements; 2) Promoting multi-stakeholder engagement and co-creation throughout the whole lifecycle of medical AI algorithms; 3) Creating an AI passport and traceability mechanisms for enhanced transparency and trust in medical AI; 4) Developing frameworks to better define accountability and monitor responsibilities in medical AI; 5) Introducing education programmes to enhance the skills of healthcare professionals and the literacy of the general public; 6) Promoting further research on clinical, ethical and technical robustness in medical AI; and, 7) Implementing a strategy for reducing the European divide in medical AI (European Parliament, 2022, V-VI)

Legal regulation of use of artificial intelligence in healthcare and medicine in the European Union

One of the first proposed regulations for risk assessment in the field of AI appeared in 2018, when the commission for data ethics in Germany suggested that the risks of general decision algorithms are classified on the basis of criticality, that is, the system's potential to cause damage. In March 2024

the European Parliament adopted the Artificial Intelligence Act[2], and the Council of the European Union approved it in May 2024. This is the first comprehensive EU regulation on AI. It regulates AI in general, for different sectors. The mentioned documents classify AI tools based on the proportionate risk-based approach including 4 level of risks: unacceptable risk, high risk, limited risk and minimal or no risk (European Commission, 2024, 2).

The *unacceptable risk* is prohibited. AI systems which are considered a threat to people fall under this group. Prohibited AI system is system that "deploys subliminal techniques beyond a person's consciousness or purposefully manipulative or deceptive techniques, with the objective, or the effect of materially distorting the behaviour of a person or a group of persons by appreciably impairing their ability to make an informed decision, thereby causing them to take a decision that they would not have otherwise taken in a manner that causes or is reasonably likely to cause that person, another person or group of persons significant harm" (AI Act, art. 5). Under this category is also AI system that "exploits any of the vulnerabilities of a natural person or a specific group of persons due to their age, disability or a specific social or economic situation, with the objective, or the effect, of materially distorting the behaviour of that person or a person belonging to that group in a manner that causes or is reasonably likely to cause that person or another person significant harm" (AI Act, art. 5). AI systems which are prohibited are those that entail unacceptable scoring practices leading to detrimental or unfavourable outcomes (AI Act (31)). More precisely, social scoring of natural persons by public or private actors that may "violate the right to dignity and non-discrimination and the values of equality and justice" (AI Act (31)). "Such AI systems evaluate or classify natural persons or groups thereof on the basis of multiple data points related to their social behaviour in multiple contexts or known, inferred or predicted personal or personality characteristics over certain periods of time. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour" (AI Act (31)). It is prohibited to use AI system to generate risk assessment of natural persons for predicting the risk of committing the criminal offence "based solely on the profiling of a natural

[2] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

person or on assessing their personality traits and characteristics" (AI Act, art. 5). Use of AI systems which "create or expand facial recognition databases through the untargeted scraping of facial images from the internet or CCTV footage" is also banned (AI Act, art. 5). It is also not allowed to use AI systems for interfering with emotions within the workplace and education institutions, with the exception when it is used for medical or safety reasons (AI Act, art. 5). Restrictions are placed on certain usage of biometric categorisation systems and real-time remote biometric identification systems (see: AI Act, art. 5).

Category of AI systems with *high risk* are those that have a significant potential to cause harm. The high risk can be the AI system which is intended to be used as a safety component of a product, or the AI system which is itself a product (AI Act, art. 6). The stand-alone AI systems can be classified as high-risk if, "in light of their intended purpose, they pose a high risk of harm to the health and safety or the fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence" (AI Act (52)). Of particular importance for classifying an AI system as high risk is the extent of the adverse impact it causes on fundamental rights protected by the Charter of Fundamental Rights of the European Union.[3] When assessing the severity of the harm, it is important also to consider the fundamental right to a high level of environmental protection which is implemented in EU policies, and to assess it especially in relation to health and safety (AI Act (48)). AI systems which are of high risk shall comply with the requirements prescribed by the AI Act.[4]

AI systems with *limited risk* are those which entail risk of manipulation or deep fakes. Therefore, there are specific transparency requirements prescribed by AI Act, making sure that users are aware of the fact that they are interacting with machine (e.g. when using chatbots) (European Commission 2024). AI-generated content like text, audio and video content has to be labelled as artificially generated (European Commission, 2024, 3).

[3] "Those rights include the right to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association, the right to non-discrimination, the right to education, consumer protection, workers' rights, the rights of persons with disabilities, gender equality, intellectual property rights, the right to an effective remedy and to a fair trial, the right of defence and the presumption of innocence, and the right to good administration. In addition to those rights, it is important to highlight the fact that children have specific rights as enshrined in Article 24 of the Charter and in the United Nations Convention on the Rights of the Child, further developed in the UNCRC General Comment No 25 as regards the digital environment, both of which require consideration of the children's vulnerabilities and provision of such protection and care as necessary for their well-being" (AI Act (48)).

[4] For more details see Section 2 to 5 of the AI Act.

Minimal or no risk AI systems can be used freely. Those are systems that do not fall into previous categories. One of the examples of such systems is spam filter (European Commission, 2024, 3).

Some parts of AI Act relate to medicine and healthcare. Namely, high risk AI systems which are subject to the strictest regulatory requirements are "AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for essential public assistance benefits and services, including *healthcare services*, as well as to grant, reduce, revoke, or reclaim such benefits and services" (AI Act, ANNEX III). The high-risk are also "AI systems intended to evaluate and classify emergency calls by natural persons or to be used to dispatch, or to establish priority in the dispatching of, emergency *first response* services, including by … *medical aid*, as well as of *emergency healthcare patient triage systems*" (AI Act, ANNEX III). Medical devices and in vitro diagnostic medical devices also belong to the high-risk group (AI Act, (50)).

Regulations which were applied for medical AI tools before enactment of AI Act are still applicable in this field. Those are Medical Devices Regulation[5] and In Vitro Diagnostic Medical Devices Regulation.[6] The AI Act should complement those regulations especially as "machinery or medical devices products incorporating an AI system might present risks not addressed by the essential health and safety requirements set out in the relevant Union harmonised legislation, as that sectoral law does not deal with risks specific to AI systems" (AI Act, (64)).

Use of artificial intelligence in healthcare and medicine – case of Serbia

In December 2019, the Government adopted Strategy for the Development of Artificial Intelligence in the Republic of Serbia for the period 2020-2025. The Strategy defines objectives and measures for the development of AI (Strategy for the Development of AI, 1). Implementation of those measures should enable development and application of AI "in a safe manner and in accordance with internationally recognized ethical principles, in order to exploit the potential of this technology to improve the quality of life of each

[5] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1–175.

[6] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017, p. 176–332.

individual and the society as a whole, as well as to achieve Sustainable Development Goals" (Strategy for the Development of AI, 1).

At the time when the Strategy was adopted the EU Artificial Intelligence Act has not yet been enacted, so the Strategy was aligned with the European Artificial Intelligence Initiative.

The Strategy does not deal specifically with the issue of the use of AI in healthcare and medicine. When evaluating the current situation in the key sectors on which the development of AI can have an impact and in which it can bring the greatest benefits, healthcare and medicine is identified as one of the key areas within the public sector. But there is no detailed analysis of the application of AI in this area. It is just stated that "in the healthcare system, artificial intelligence can significantly enhance early diagnostics, it can ensure better availability of all resources and equipment and optimize their use, and it can contribute to the enhancement of the quality and efficiency of health services" (Strategy for the Development of AI, 17). The Strategy aims for special support for research and innovations in the fields which have a special potential for innovative use of artificial intelligence, and one of those fields is health (Strategy for the Development of AI, 30). Health and medicine are also identified as area which is of public interest for application of AI, and therefore should be specifically and primarily supported (Strategy for the Development of AI, 35).

The need for flexible regulatory framework for testing the innovative solutions and business models which are based on AI is also recognised in the Strategy. In the field of health "24-hour approval for importing unregistered medical devices for the needs of research and development under certain conditions" was introduced by Medicines and Medical Devices Agency of Serbia (Strategy for the Development of AI, 2019, 36-37).

There is necessity to pass a law which will regulate in detail the introduction and application of AI in various areas. Besides that, it is essential to regulate the application of AI in healthcare and medicine. Current legislation in this field does not deal with use of AI.

Health Care Law (Official Gazette 25/2019) defines health technologies in general, stating that they are all health methods and procedures that can be used in order to improve people's health in prevention, diagnosis, treatment, health care and rehabilitation of the sick and injured, which include safe, high-quality and effective drugs and medical means, medical software, medical procedures, as well as conditions for their application (Art. 48). It is prescribed that health care institutions and private practices are obliged to apply scientifically proven, verified and safe health technologies in prevention, diagnosis, treatment, health care and rehabilitation of the sick and injured (Art. 48). Health Care Law also defines health technology assessment which

is the comparison of new technology with the technology used in practice or considered the best possible ("gold standard"), based on clinical effectiveness and safety, economic analyses, ethical, legal, social and organizational consequences and effects (Art. 48). The assessment of health technologies and the provision of opinions on the assessment of health technologies are carried out by the Institute for Public Health established for the territory of the Republic of Serbia (Art. 49).

Rulebook with detailed conditions, the method of assessing health technologies and giving opinions, as well as other issues that are more closely regulated by the assessment of health technologies, is adopted by minister of health, on the proposal of the Republic Institute for Public Health (Official gazette 97/2020, 77/2021, 89/2021 and 33/2022). The Rulebook should be discussed and potentially revised in line with the emerging trends related to AI. This is especially related to the definition of the new health technologies, description and technical characteristics of the new medical device, etc.

Relevant act in this sense is also Law on Patients' Rights (Official Gazette 45/2013 and 25/2019). According to this Law patient has the right to information, about the state of his health, the health service and the way he uses it, as well as all information that is available based on scientific research and technological innovations (Art. 11). He/she also has the right to confidentiality of all personal information, which he/she has communicated to the competent healthcare worker, healthcare associate, including those related to his/her health condition and potential diagnostic and therapeutic procedures, as well as the right to the protection of his/her privacy during the implementation of diagnostic tests and treatment as a whole. It is forbidden for the competent healthcare worker and healthcare associate to communicate personal information to other persons (Art.14).

The problem might occur if the personal information is not processed by the health professional, but by the AI. Therefore, there is a need to change this provision in expecting the changes in health sector due to use of AI.

According to the law, patient has the right to freely decide on everything concerning his/her life and health, except in cases where that directly threatens the life and health of other persons. Without the patient's consent, as a rule, no medical measure may be taken on him/her. Medical measures against the will of the patient, i.e. the legal representative of the child, i.e. the patient deprived of legal capacity, can be taken only in exceptional cases, which are established by law and which are in accordance with medical ethics (Art. 15).

Having in mind the provisions of the national regulation on liability, it is questionable who is the liable person if the consent is obtained for one measure, which, due to the functionalities of AI, lead to other measures that were not covered by consent. Therefore, not only The Law on Patients' Rights, but

also Law on Obligations (Official Gazette SFRJ, 29/78, 39/85, 45/89 and 57/89, Official Gazette SRJ 31/93, Official Gazette SCG, 1/2003 and Official Gazette RS, 18/2020) should be amended with regards to the liability for damage caused by the AI use. Law on Obligations contains division in civil liability for damage: liability on the basis of negligence, objective liability (from dangerous thing or activity) and liability for other persons acts. The question of liability in this case of harm caused by AI systems in medicine is very important, as AI may incorrectly diagnose or suggest inappropriate medical treatment due to inaccuracies in the system. The lack of precise regulation is an issue not only in Serbia, but also in other national and international legislations, as mentioned in the subchapter related to risks. Assigning responsibilities between healthcare professionals and AI developers in the search for an answer to question "who *should be held accountable or liable for errors or failures of AI systems, especially in medical AI"* (European Parliament, 2022, II) is a very challenging task.

Patients have also the right to confidentiality of data on the state of their health, that is, data from medical records, which belong to personal data and represent particularly sensitive data about the patient's personality.[7] These data are required to be kept by all healthcare workers, i.e. healthcare associates, as well as other persons employed in healthcare institutions, private practice, organizational unit of a higher education institution of the healthcare profession that performs healthcare activities, another legal entity that performs certain tasks from the health sector, the mandatory health insurance organization, as well as the legal entity that performs voluntary health insurance, with whom the patient is health insured, and to whom such data is available and necessary for the exercise of competences established by law (Law on Patients' Rights, Art. 21). The mentioned persons, as well as other persons who, without authorization, i.e. without the consent of the patient or legal representative, dispose of data from medical records in violation of Law on Patients' Rights, and disclose such data to the public without authorization, are responsible for the release of particularly sensitive data (Law on Patients' Rights, Art. 21).

When it comes to the legal aspects of using AI in medicine, it is important to note that clinical picture support software collects information from patients' health data, allowing it to make suggestions for other patients.[8] Therefore, "the physician must address potential confidentiality and privacy

[7] Data on human substances, on the basis of which the identity of the person from whom they originate, can be determined as particularly sensitive data about the patient's personality (Law on Patients' Rights, Art. 21).

[8] https://attorney.rs/pravna-regulativa-vestacke-inteligencije-ai/

concerns, as patients have the right to understand the ways in which their confidential health information is used for research, diagnosis, and treatment purposes".[9]

Patient has also the right to consent to medical research and this is elaborated in the Art. 25 of the Law on Patients' Rights (Official Gazette RS, nos. 45/2013 and 25/2019). However, it should take into consideration also the emergence of biobanking and large medical databases driven by AI, which render it either impossible to obtain traditional informed consent from all participants, or possible, but burdensome and very time-consuming. It may be difficult to locate people, which can result in high drop-out rates (Kaye et al., 2015, 1). Several more issues are disputable with traditional consent: secondary use of data or samples; consent of participants who have passed away; right to withdrawal of consent when data has already been shared widely; possibility of re-identification when the person consented to processing of data, if coded or anonymized. Furthermore, combining genomic data from patients and family members is valuable because of its comprehensiveness, but this requires obtaining informed consent for data sharing from all participants whose data contribute to the dataset (Takashima et al,, 2018, 2).

Medical progress is a public good, so it seems necessary to change from one form of consent to another which is better adapted to contemporary research. On the other hand, if one cares only about medical progress as a public good, and not about the reliability of measures to make consent a real precondition of research, then researchers might be left unable to obtain either samples or personal data (Wiertz & Boldt, 2022, 274). IT can be used to satisfy legal and regulatory requirements for research consent, while at the same time providing a personal communication interface for interacting with patients, participants and citizens. So far, besides traditional consent, several more forms of consent are being developed, which are better adapted to medical progress: specific consent, broad consent, dynamic specific consent, tiered consent, meta consent. All of them have their positive and negative aspects. Their adaptability to the specific situation has to be assessed on the basis of the functionalities of the specific consent model, but also on the basis of the context of consent (Wiertz & Boldt, 2022, 277).

Use of AI in healthcare and medicine in practice in Serbia

Companies that are engaged in digitalisation of the healthcare system in Serbia are working on introduction of AI in healthcare: "The use of artificial

[9] https://attorney.rs/pravna-regulativa-vestacke-inteligencije-ai/

intelligence in healthcare is on the rise, and the greatest potential exists in the domain of differential diagnosis, therapy selection, risk prediction, reduction of medical errors and improvement of productivity…. citizens will be able to use their mobile phones as a kind of digital health platform, actively and passively documenting their health in detail and in real time. The next step is the processing and analysis of the collected data by artificial intelligence" (Naled, 2023, 1).

When doing so, Government tending towards digitalisation in healthcare and engaged companies should take precaution measures not to overstep legal and ethical boundaries posed by different legislation levels.

Although national legislation is not developed in this area (except mentioned Strategy, which does not deeply tackle digitalisation in healthcare), there are several mentioned acts on the EU level, and literature focusing on challenges of digitalisation in healthcare (mentioned above).

The EU AI Act has been adopted only few months ago, so Serbian legal regulations have yet to be harmonized. As the Strategy for the Development of Artificial Intelligence in the Republic of Serbia for the period 2020-2025 was aligned with the European Artificial Intelligence Initiative, as the AI Act has not been adopted at that time, we can assume that the future legislation in Serbia will be in line with the EU legislation in the field of AI. Some influence of AI Act can already be seen in the guidelines adopted last year.

In February 2023, the Government of the Republic of Serbia adopted the Ethical guidelines for the development, implementation and use of reliable and responsible artificial intelligence. In March last year, the Government adopted the Conclusion adopting *Ethical guidelines for the development, application and use of reliable and responsible artificial intelligence* (Vlada RS, 2023) (hereinafter: Guidelines). Their goal is to introduce a preventive mechanism that will enable the responsible development of this type of intelligence and ways of verifying that the systems are based on machine learning in accordance with the highest ethical and safety standards. Guidelines are not specifically focused to healthcare, but mention health care as one of the high-risk systems, especially systems that analyse genetic and health data. A high-risk system is a system that has a tendency to directly or indirectly violate the principles and conditions established by the Guidelines, but does not necessarily do so. From the point of view of the Guidelines, high-risk systems are not considered undesirable, but precisely because of the aforementioned impact, the importance of the areas of life in which they are applied, and the possibilities and range of influence on man and his integrity, it is necessary to analyse them separately and evaluate their impact (Vlada RS, 2023, 2.3).

Guidelines lists the principles which are the starting point for the creation, application and use of artificial intelligence systems that will be worthy of human trust due to their reliability and responsibility towards humans. The conditions for reliable and responsible AI are also listed and specified in details: 1. Action (mediation, control, participation) and supervision; 2. Technical reliability and safety; 3. Privacy, personal data protection and data management; 4. Transparency; 5. Diversity, non-discrimination and equality; 6. Social and environmental well-being; 7. Liability (Vlada RS, 2023, 4).

Connoisseurs of opportunities in the tech market of Serbia believe that the new law (EU AI Act) will not significantly change opportunities in the domestic IT market, nor in the use of AI technologies in everyday life.[10]

The AI Act could become a global standard, like the EU General Data Protection Regulation (GDPR). On the other hand, it is necessary that standardization organizations work dedicatedly to support in application of the law on artificial intelligence. A common terminology of agreed terms (words and expressions) is a prerequisite for the successful development of AI standard documents.[11]

Conclusion

The advancement of technology in the last few decades has brought significant changes in various fields, especially in medicine and healthcare. The application of AI in medicine and healthcare has, on the one hand, brought numerous benefits, but on the other hand it has also opened up different questions, primarily in terms of the safety of their application. This also led to the question of whether the traditional way of legal regulation in the field of medicine and healthcare can be applied when it comes to new AI technologies and medical tools. The results of the research showed that it is necessary to change the existing legislation and/or adopt a new one that would be in accordance with the newly created changes. Based on the research that we conducted it can be concluded that the legal regulation does not keep pace with the changes brought by innovations, such as the application of AI in medicine and healthcare, but the legislation in this domain lags behind the real needs. New AI Act at the EU level, as the first comprehensive act that regulates use of AI systems, have brought important changes. However, it is regulating the use of AI in healthcare and medicine only through high-risk AI systems. The previous legislation which existed in this field is still appli-

[10] https://www.helloworld.rs/blog/Srbija-jos-bez-zakona-o-vestackoj-inteligenciji-ali-ocekuje-se-uskladjivanje-sa-EU/19165

[11] https://attorney.rs/pravna-regulativa-vestacke-inteligencije-ai/

cable. There is necessity to regulate use of AI in medicine and healthcare more precisely, both at the international and national level. As we emphasized in this paper, it is of special importance to regulate the issue of liability in this field.

We analysed current health legislation in Serbia and based on results of our research we can conclude that changes have to be made in order to regulate the use of AI in healthcare and medicine. Some first steps were made through strategies, but concrete, specific and obligatory regulation in this field is lacking. It seems that challenges are clear, but the solutions are not still there. Beside aligning national legislation with new EU AI Act, national legislator should bring together IT, medical and legal professionals in the joint working group, i.e. create multisectoral surrounding, which would work together on the specific nation-tailored legal solutions within the general internationally accepted framework. This seems to be the only way in which professions will understand each other's language and develop legal framework which would enable basis for technological advancement parallelly with real and users-friendly safety and security measures. The initiation of such effort has already been made by establishing the Council for Artificial Intelligence by the Government of RS. Its task will be to harmonize and coordinate activities for the implementation of the strategic framework in the field of artificial intelligence development. The task of the Council will also be to monitor the implementation of planned measures and activities, monitor the state, needs and standards of the development and application of artificial intelligence in RS and the world. The Council will have an advisory role and prepare proposals, recommendations and standards, give opinions and expert explanations on all issues in the field of development and application of artificial intelligence in RS.[12] There are, however, still steps to be made related to implementation of this task in the field of medicine.

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