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# THE APPLICATION OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE: DIAGNOSTIC POTENTIAL, LEGAL FRAMEWORK AND ETHICAL CHALLENGES***

## Abstract

Artificial intelligence (AI) has assumed an increasingly significant role in contemporary society, particularly within the healthcare sector. While the medical community was initially hesitant to embrace advanced technologies, recent years have witnessed a rapid expansion in the integration of AI into clinical practice. This development has the potential to fundamentally reshape the ways in which diseases are diagnosed, treated, and predicted. Given that the fight against malignant diseases constitutes one of the European Union's central health policy priorities, as articulated in the strategic document *Europe's Beating Cancer Plan*,

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this paper explores the potential of AI to advance the objectives of that agenda, with particular emphasis on enhancing screening programmes and fostering the development of personalised therapeutic approaches. The paper is organised into three thematic sections. The first section adopts an empirical approach to investigate the potential of AI in a clinical context, with a particular focus on improving diagnostic accuracy and advancing predictive analytics. The second section employs a comparative legal methodology to analyse the regulatory frameworks governing the application of AI in the healthcare systems of the Republic of Serbia and the Republic of North Macedonia. The third section addresses key ethical challenges, including the protection of patient privacy, the mitigation of algorithmic bias, and the safeguarding of informed consent in a technology-mediated medical environment. The methodological framework of this paper is primarily grounded in qualitative analysis, encompassing both legal instruments and relevant professional and academic literature, while incorporating quantitative evidence to the extent that it is available through existing medical research.

**Keywords:** artificial intelligence, screening program, personalized treatment, patient informed consent, patient data protection

## INTRODUCTION

The term *Artificial Intelligence* (AI) was first introduced by John McCarthy at a conference held at Dartmouth College in 1956 (Prlja, Gasmi, i Korać 2021, 58). On that occasion, McCarthy defined artificial intelligence as the capacity of a computer to perform specific tasks and objectives through various learning and programming mechanisms (McCarthy 2007, 1176–1177). In other words, artificial intelligence denotes the advancement of technology to a level at which it can independently carry out certain functions traditionally associated with human intelligence (Sovilj i Stojković-Zlatanović 2023, 225; Stjepanović 2024, 186). AI thus seeks to replicate human cognitive processes in order to address complex problems. Within decision-making, it engages in data processing tasks that closely resemble those employed by human cognition (Scherer 2016, 359–362). Processes such as logical reasoning, problem-solving, learning from prior experience, and even natural

language interpretation form part of the algorithmic framework that underpins AI-based decision-making (Andonović 2020, 113).

From its inception to the present day, artificial intelligence has evolved at an extraordinary pace, becoming an integral component of numerous domains of contemporary society. Among these, medicine represents a field in which AI has exerted a particularly profound influence. While the integration of AI into healthcare systems promises significant advantages, enhancing efficiency, diagnostic precision, and the delivery of personalised treatment, it simultaneously generates complex legal and ethical challenges. As Wohlthat (2020, 20) observes, AI may affect healthcare in four principal areas: diagnostics, the automation of medical tasks (including robot-assisted procedures), therapeutic decision-making, and biopharmaceutical innovation. In practice, AI applications are already evident in clinical diagnostics and auxiliary healthcare processes, such as patient triage, appointment scheduling, medical record management, and postoperative monitoring.

The application of artificial intelligence in medicine is particularly significant in oncology, given the complexity of malignant diseases and the imperative for rapid and precise diagnosis. Recognising cancer as a major public health challenge, the European Union has adopted the strategic document *Europe's Beating Cancer Plan*, which encourages Member States to advance early detection and treatment initiatives and to ensure equitable access and outcomes for patients (Vukadinović Marković 2024, 482–483). Within this framework, AI is emerging as a pivotal tool capable of supporting early disease detection, personalised therapeutic strategies, and more effective patient monitoring. Among its earliest and most successful applications is diagnostic radiology (Gulshan *et al*. 2016, 316). AI systems can analyse thousands of magnetic resonance, CT scans, and mammography images in a fraction of the time required for human assessment, while demonstrating the capacity to detect even the smallest anomalies across extensive datasets. This capability underscores the enormous potential of AI in identifying early-stage pathological changes associated with melanoma (Srinivasu *et al*. 2021, 2852) and prostate cancer (Saha *et al*. 2024). Particularly encouraging outcomes have been observed in the application of AI to the early detection of breast cancer (Vulli *et al*. 2022, 2988; Shah *et al.* 2022; Ahn *et al*. 2023).

Breast cancer remains one of the leading causes of mortality among women in the European Union, accounting for approximately

85,000 deaths annually. Studies indicate that AI software can interpret mammograms up to 30 times faster than human radiologists, achieving 99% accuracy and significantly reducing both false positives and false negatives in mammography screening. Given that Serbia exhibits an exceptionally high incidence of breast cancer, around 4,000 new diagnoses per year, and that the disease is often detected at advanced stages, specific measures must be implemented to ensure earlier detection (Miljuš, Živković-Perišić, i Božić 2022, 15). With current waiting times for mammography and magnetic resonance imaging extending up to six months, the deployment of AI could substantially reduce these delays. Where double reading of mammograms is required, AI can serve as a secondary reader, which is of critical importance in settings experiencing shortages of trained radiologists (Griffiths 2016). Moreover, AI technologies integrated with advanced deep learning models can further enhance the detection of ductal breast carcinoma, improving both the accuracy and reliability of image interpretation (Praveen *et al*. 2022). Beyond imaging, AI is increasingly applied to the analysis of genomic, histopathological, and clinical data, facilitating more precise tumour classification and enabling the prediction of patient-specific responses to the prescribed therapies.

## Precision Medicine and AI-Driven Predictive Medical Analytics

Precision medicine represents a key domain in which AI is extensively applied, as it enables personalised healthcare and clinical decision-making tailored to patients' unique genetic, biochemical, and psychological profiles. In this context, clinicians first analyse the results of patients' genetic tests, which may be facilitated by AI, and subsequently employ algorithms to determine the most effective therapeutic strategy based on individual characteristics. This approach allows for the provision of so-called personalised therapies, which are particularly crucial in oncology (Kraft 2019, 30). Personalised therapy involves the use of drugs specifically designed to act in a targeted manner, taking into account the patient's genetic predisposition, thereby enhancing therapeutic efficacy while reducing the risk of adverse effects (Johnson *et al*. 2021).

Predictive testing further enables the assessment of disease risk, supporting the implementation of individualised preventive

interventions. Liquid biopsy, a non-invasive diagnostic technique that analyses circulating DNA in the blood to detect early signs of malignant disease recurrence, occupies a prominent place in contemporary oncology (Gentile and Malara 2024).[1] Early detection of disease facilitates timely intervention, improves treatment outcomes, and significantly reduces overall healthcare costs.

AI also contributes to the monitoring of therapeutic regimens. For instance, applications that track medication adherence by transmitting images when doses are taken can verify correct administration and enable immediate intervention in the event of non-compliance (Kostić, Pavlović, and Živković 2019, 131).

Beyond its role in monitoring therapeutic regimens, AI is increasingly being applied to predictive modelling. For the first time in the Macedonian healthcare system, a predictive model has been developed that employs artificial intelligence to anticipate complications following stem cell transplantation. This model, intended for integration into future clinical practice, holds the potential to markedly reduce transplantation-related mortality. In particular, it is designed to estimate the risk of acute graft-versus-host disease (GvHD) after allogeneic haematopoietic stem cell transplantation through the application of machine learning techniques. The project is being carried out by a team of three Macedonian researchers: two physicians based in Macedonia and a professor from the United States (Здравковска 2025).

Allogeneic haematopoietic stem cell transplantation has been part of the Macedonian healthcare system for 25 years. It represents one of the most complex biological interventions in human medicine, involving the replacement of a patient's own cells with those of a healthy donor. The primary objective of this procedure is the treatment of severe conditions such as leukaemia, multiple myeloma, lymphomas, aplastic anaemia, and myeloproliferative disorders.

Acute GvHD remains among the most frequent and severe complications of allogeneic haematopoietic stem cell transplantation. It

[1] The introduction of liquid biopsy has significantly advanced the field of oncological surveillance, enabling highly precise and synchronised monitoring of carcinoma initiation and progression. This development has redefined the conceptualisation of cancer risk, which was traditionally attributed to an interplay of favourable and adverse lifestyle factors. Within the contemporary paradigm of biological safety, however, such risk is increasingly quantified through the analysis of biomarkers reflecting cellular injury.

arises when the donor's immune cells (the graft) mount an attack against the recipient's tissues (the host), perceiving them as foreign. While transplantation provides the patient with a "new immune system," this system does not always align with the host body. The spectrum of disease severity ranges from mild manifestations to life-threatening forms. Epidemiological data indicate that acute GvHD develops in 30–50% of patients undergoing allogeneic transplantation, particularly in cases where the donor is unrelated.

Modern medicine relies on immunosuppressive therapy treatments that dampen the immune response to prevent or alleviate the onset of GvHD. Yet, such interventions inevitably heighten vulnerability to infections and other complications. The present project seeks to develop algorithms grounded in clinical data, genetic markers, and transplantation-specific characteristics, with the goal of generating an individualized risk profile for each patient. These predictive models are expected to facilitate timely intervention and substantially reduce mortality associated with transplantation.

Beyond the context of transplantation, artificial intelligence also holds significant promise for patients living with chronic diseases, supporting more independent management of their health. This is of exceptional importance for every cancer patient, both medically and sociologically (Vukadinović Marković, Radomirović, i Stjepanović 2025). Systems such as patient support tools, digital assistants, and predictive applications for symptom monitoring enable patients to play a more active role in managing their health. However, it is important to emphasise that digitising healthcare should never replace the traditional doctor–patient relationship, which is based on trust and empathy. In addition to ethical dilemmas, the application of AI in medicine raises a whole host of legal issues. These range from protecting privacy rights and addressing algorithmic bias and oversight to determining liability for wrong decisions resulting from AI recommendations (Sovilj 2023, 16; Stjepanović 2025, 189).

## LEGAL REGULATION OF AI IN HEALTHCARE

The deployment of artificial intelligence in medicine gives rise to a broad spectrum of legal and regulatory challenges, necessitating the development of robust governance frameworks. In 2021, the World Health Organization (WHO), as the leading international health

authority, adopted the *WHO Guidelines on Ethics and Governance of Artificial Intelligence for Health* (Ethics and Governance of Artificial Intelligence 2021). These guidelines emerged from an 18-month consultative process involving experts in ethics, technology, law, human rights, and healthcare. They identify the principal ethical challenges and risks associated with AI and articulate six fundamental principles for its responsible use in healthcare. Furthermore, the guidelines provide recommendations for the establishment of effective management systems that ensure accountability while safeguarding the rights of both healthcare professionals and patients. A significant milestone in the regulation of artificial intelligence at the European Union level was reached on 24 January 2024, when the European Commission established the European Artificial Intelligence Office. This Office is tasked with overseeing the development of AI models, including general-purpose models, and fostering collaboration with scientific and professional communities. It will also engage in research and testing, ensure compliance with legal regulations, and operate with a view toward global standards (Dabić 2025, 221). The Office is expected to serve as a central hub of AI expertise within the Union and to lay the groundwork for a unified European system to govern this technology (Dabić 2025, 226).

Shortly after its establishment, on February 2, 2024, the Council of the European Union unanimously adopted the Regulation on the Harmonisation of Rules on Artificial Intelligence (commonly referred to as the Artificial Intelligence Act), thereby initiating the final stage of the legislative process (Regulation 2024/1689). The Regulation entered into force on August 1, 2024, and is scheduled to become operational 36 months later, on August 2, 2027.[2] Under the AI Act, AI systems are categorised according to risk level, ranging from unacceptable and high to limited and minimal, establishing the highest global standards of protection (Schneeberger, Stöger, and Holzinger 2020, 212).

Additionally, the Regulation on the European Health Data Space (Regulation 2025/327), which entered into force on March 26, 2025, merits particular attention. Its objective is to create a secure, interoperable, and ethically designed framework for the exchange of health data within the European Union.

[2] This primarily refers to Article 6, which categorizes high-risk artificial intelligence systems, including, among others, healthcare, and establishes strict requirements concerning conformity assessment, risk management, transparency, human oversight, and data quality (Regulation 2024/1689, Art. 6).

Building on the aforementioned European Union regulations, the governance of artificial intelligence in healthcare also relies on other key EU instruments, such as the General Data Protection Regulation (Regulation 2016/679), the Data Protection Act (Regulation 2022/868), and mechanisms safeguarding privacy and patient rights.

## Regulation of Artificial Intelligence in the Republic of Serbia

The regulatory framework for artificial intelligence in the Republic of Serbia is gradually evolving in alignment with international standards. The *Strategy for the Development of Artificial Intelligence in the Republic of Serbia (2020–2025)* (Strategija za razvoj veštačke inteligencije u Republici Srbiji za period 2020–2025 [SRVIRSP 2020–2025] 2019), adopted by the Government of Serbia in December 2019, constituted the foundational policy document in this domain. It delineated the objectives and actions aimed at promoting the development and application of AI, while also establishing the groundwork for a future AI-specific legal framework. In January 2025, the Government adopted the new AI strategy, extending the development plan for artificial intelligence in Serbia for the period 2025–2030.

The 2020–2025 Strategy outlines measures designed to facilitate the safe implementation of artificial intelligence in accordance with internationally recognised ethical principles (Nikolić Popadić i Sjeničić 2024). The 2025–2030 Strategy explicitly provides that "the measures include special support for the application of artificial intelligence solutions in the fields of health and biotechnology" (SRVIRSP 2025–2030 2025, mera 6.7). The preceding 2020–2025 guidelines had already identified healthcare and medicine as priority sectors within the public domain, although they did not provide a detailed analysis of AI applications in these areas. According to these guidelines, "in the healthcare system, artificial intelligence can significantly enhance early diagnosis, ensure improved accessibility to resources and equipment, optimise their utilisation, and contribute to the overall quality and efficiency of healthcare services" (SRVIRSP 2020–2025 2019, čl. 3–4).

Further steps towards the effective implementation of artificial intelligence in Serbia are reflected in the *Ethical Guidelines for the Development, Application, and Use of Reliable and Responsible Artificial Intelligence*, adopted by the Government of Serbia in February 2023 and formalised by a special conclusion in March of the same year (Zaključak

o usvajanju etičkih smernica za razvoj, primenu i upotrebu pouzdane i odgovorne veštačke inteligencije [ZUESRPUPOVI] 2023), hereinafter referred to as the "Guidelines." The Guidelines seek to establish a regulatory framework that promotes the responsible development of AI and introduces mechanisms to ensure compliance with the highest ethical and safety standards. Although the Guidelines do not focus exclusively on the healthcare sector, they recognise healthcare as a high-risk domain (ZUESRPUPOVI 2023, čl. 2–3). While the use of AI is not inherently detrimental, its potential impact on fundamental human rights necessitates special oversight and a comprehensive impact assessment prior to implementation.

In the context of processing patient data, ensuring compliance with the provisions of the Law on the Protection of Patients' Rights (Zakon o pravima pacijenata 2019) is of particular importance. Article 11 (čl. 11) of the Law guarantees patients the right to be informed about their health status and the healthcare services available to them, including information on how to access these services. It also ensures patients' right to access all information derived from scientific research and technological innovations. Furthermore, Article 14 (čl. 14) guarantees the confidentiality of information entrusted by patients to healthcare professionals, including details concerning diagnosis and therapy. Such information may not be disclosed to third parties without the patient's explicit consent.

Given the increasing integration of AI technologies in healthcare, it is imperative to review existing legal provisions, particularly those relating to informed consent, and to adapt them to address contemporary challenges arising from the digitalisation and automation of medical practice.

## Regulation of Artificial Intelligence in North Macedonia

In September 2021, at the initiative of the Fund for Innovation and Technological Development (FITR), the leading government institution supporting start-ups and innovative companies in the Republic of North Macedonia, a working group was established to develop the country's first National Artificial Intelligence Strategy, bringing together both domestic and international experts. However, since its inception, the group has convened only once. The strategy is envisaged as part of North

Macedonia's broader economic development agenda and is aligned with the National Development Strategy 2021–2041.[3]

The State Audit Office (DZR), in its June 2025 performance audit report *Opportunities for the Use of Artificial Intelligence in the Public Sector* (Конечен извештај за извршена ревизија на успешност на тема *Можност за употреба на вештачка интелигенција во јавниот сектор* 2025) concluded that North Macedonia lacks a strategy, legal framework, and adequate infrastructure for the application of artificial intelligence in the public sector despite the pressing need for them.[4]

In 2024, the Ministry for Digital Transformation was established as the successor to the former Ministry for Information Society and Administration. One of its first tasks has been to revive the initiative for a National Artificial Intelligence Strategy and to oversee the rapid adoption of the Strategic Action Framework for the Use of Artificial Intelligence. This framework is envisioned as a government resolution, setting out concrete tasks and activities across various sectors and institutions, including education, healthcare, technology, and others, where AI tools may be applied.

Within the broader context of digital transformation and the national strategy for the development of information and communication technologies, the use of artificial intelligence in healthcare is particularly emphasized. Anticipated applications include the modernization of the healthcare system through algorithms for early diagnosis, automated analysis of medical imaging (such as X-rays and MRIs), the development of personalized treatments, AI-based healthcare assistants, and the optimization of hospital and healthcare resource management.

Nevertheless, the Minister for Digital Transformation and the Government have taken the position that there is currently no need for specific legislation governing artificial intelligence in North Macedonia, despite this being one of the observations and recommendations made in the report of the Digital Transformation Agency. The justification

[3] In terms of innovation, the government launched *ADA* in 2023, the first AI-powered digital assistant in the public sector, designed to enhance transparency and provide information on investment opportunities. Despite an investment of €150,000 in its development and maintenance, the tool has since been discontinued (Digital Public Administration Factsheets – North Macedonia 2024).

[4] Between 2018 and 2023, FITR co-financed 48 projects worth a total of €6.11 million, none of which were implemented within state institutions. As a result, the public sector has derived no tangible benefit from these investments (Annual Report on performed audits and operations of the State Audit Office 2024 2024).

offered is that AI remains a highly dynamic and relatively unpredictable technology, still in exponential development.

For now, the regulation of artificial intelligence is seen as a global challenge for both science and policy experts. Accordingly, the state's priority should be to actively monitor international developments, align with global trends, and gradually transpose international legal instruments into domestic law. In the interim, the emphasis should be placed on establishing robust ethical standards for AI use, safeguarding personal data, and promoting digital skills.

In terms of patient data processing, the Law on the Protection of Patients' Rights in North Macedonia is aligned with the GDPR (Закон за заштита на правата на пациентите 2015). The Law regulates the collection of personal data, specifically medical data relating to a patient's health through the creation of a medical dossier. Such data includes information on the patient's medical history, diagnosis, prognosis, and treatment, as well as any other information directly and closely linked to their health.

Patients are guaranteed the right to confidentiality of both personal and medical data, which must remain protected even after their death, in line with data protection provisions. Disclosure of patient data is permitted only under limited circumstances: with the patient's written consent; where necessary for medical intervention in another institution; where required by law for processing by a healthcare institution providing services to the patient; or for historical, scientific, research, or educational purposes, provided that the patient's identity remains undisclosed. Patient data must be stored in accordance with the provisions on the protection of professional, business, and personal data confidentiality. Its processing is carried out in line with the applicable personal data protection framework (Закон на заштита на личните податоци 2021).

In light of contemporary challenges, including the ongoing digitalisation of healthcare and the increasing integration of artificial intelligence, it is crucial that existing legal provisions are updated to align with global developments. This entails the careful transposition of the latest European and international legal frameworks governing the application of artificial intelligence in healthcare.

## ETHICAL ASPECTS OF ARTIFICIAL INTELLIGENCE

While the integration of artificial intelligence into modern medicine offers a host of new opportunities, it simultaneously raises important ethical questions. Some observers express concern that AI could replace medical professionals (Sharma 2024). Yet, a comparable resistance arose in the mid-20th century with the advent of computers, which were initially perceived as a potential threat to established professions. Historical experience demonstrates that digital technologies have ultimately conferred far greater benefits than harm. Within this context, it is reasonable to anticipate that AI will, in the long term, enhance the quality of healthcare, benefiting both medical practitioners and patients.

The doctor-patient relationship, grounded not only in professional expertise but also in trust, empathy, and dedication, remains a cornerstone of ethical medical practice (Ćirić 1991, 12–13). This relationship is defined by the patient's confidence in both the attending physician and the healthcare system of a given country. Foundational ethical principles: beneficence, non-maleficence, autonomy, and justice retain central importance in clinical decision-making, particularly amid the rapid digitalisation of healthcare. The application of these principles ensures a careful balance between individual rights, societal responsibility, and the preservation of professional integrity within medicine (Radenović 2012, 20–25).

Respect for human dignity, as an inherent value of every individual, lies at the core of all ethical principles and should serve as the foundation for the development of ethical guidelines governing the use of artificial intelligence in healthcare. A central concern is the preservation of patient autonomy. Traditional medicine often relies on a one-size-fits-all approach. By contrast, artificial intelligence is driving the shift toward precision medicine, in which treatments are tailored to the genetic, environmental, and lifestyle factors of individual patients. Machine learning models analyse genetic and clinical data to predict patient responses to specific medications, thereby reducing reliance on trial-and-error prescribing.

In this context, artificial intelligence offers tools that can tailor treatments to the individual characteristics of each patient, moving beyond the limitations of traditional medicine. This approach is particularly promising in oncology, where machine learning based tools

assist oncologists in selecting the most effective therapies for patients with complex cancers. Drawing on large datasets ranging from clinical trials and historical medical records to laboratory results, machine learning can efficiently classify patients, enabling more targeted and effective treatment. It can also generate unbiased, data-driven prognoses regarding treatment outcomes.

Perhaps the greatest advantage of personalised medicine lies in its ability to simulate multiple scenarios and identify the strategy that best aligns with a patient's unique genetic profile. In the context of AI-assisted early diagnosis, it is crucial that systems operate under adequate human oversight. Otherwise, they may inadvertently limit patients' control over the decision-making process. Valid informed consent, therefore, requires patients to be thoroughly informed about how algorithms function, the data they use, and the potential consequences of their application.

The deployment of AI in clinical practice may lead to situations in which decisions are generated exclusively by machines or algorithms. Respecting autonomy requires that such systems do not diminish the control of patients and healthcare professionals over diagnostic and therapeutic processes. Systems should be developed exclusively as decision-support tools, not as substitutes for human decision-making. This entails an accompanying obligation to protect patient privacy, uphold confidentiality, and ensure that consent is both valid and fully informed.

Furthermore, critical ethical issues arise regarding decisions made solely on the basis of automated data processing. These challenges must be carefully addressed to safeguard the integrity of clinical judgment and the rights of patients.

Even when the law permits automated decision-making through AI systems, implementing the safeguards necessary to ensure patient safety often proves challenging. Most healthcare professionals lack sufficient training to fully understand the functioning of algorithmic models and are therefore unable to provide patients with accurate, comprehensible explanations. Consequently, a key element of informed consent is frequently absent (Đurđević 1997, 31), rendering patients unable to give valid consent to a particular medical intervention. In practice, valid consent requires that patients be adequately informed about their health condition, the proposed treatment options, potential outcomes, and available alternatives, with the information carefully tailored to the individual patient.

These challenges are particularly pronounced when employing robotic systems. Patients with lower levels of education may react with fear or distrust at the mere prospect of robotic involvement in medical procedures. Discovering that the physician's role is minimal or virtually absent in certain procedures may provoke discomfort, anxiety, or even panic (Kačer i Kačer 2019, 82).

Fear of dehumanisation in healthcare, where machines, rather than humans, make critical decisions, raises profound philosophical questions about the very nature of medical care. The role of healthcare professionals must therefore evolve to integrate the analytical capabilities of artificial intelligence with empathy, ethical reasoning, and moral judgement, which remain uniquely human qualities.

A further major challenge is the problem of bias in machine learning systems. Biased datasets containing structural imbalances or underrepresentation directly undermine the accuracy and fairness of algorithms trained upon them. For instance, if a medical image dataset disproportionately reflects one demographic group, diagnostic models trained on such data may produce unreliable or inaccurate results when applied to patients outside that group. This risks misdiagnoses or ineffective treatment pathways for entire populations.

Since artificial intelligence systems learn from data, they inevitably absorb the prejudices of their creators as well as societal biases embedded in the training material. Instead of correcting these tendencies, AI can perpetuate and even institutionalize them. When algorithmic decision-making occurs with minimal human oversight, responsibility may be displaced through an overreliance on computer-generated recommendations, a phenomenon often described as automation bias.

Ultimately, biased AI systems can generate algorithmic discrimination, producing inequitable outcomes or discriminatory behaviours. Moreover, if an AI model trains on historical datasets shaped by discriminatory decisions, it may reinforce those very patterns through a feedback loop, thereby jeopardising patients' rights and undermining trust in healthcare systems (Камбовски и Стојановска 2024, 21).

Meanwhile, the fundamental question of responsibility remains unresolved. When AI systems participate in medical decision-making that results in harm, the question arises as to who bears liability: the software developer, the healthcare institution, the attending physician, or the system itself? This dilemma becomes particularly pronounced as AI systems gain greater autonomy. In conventional healthcare settings,

accountability typically rests with the medical institution. To prevent the diffusion of responsibility where "everyone is responsible, but ultimately no one is held accountable," it is essential to establish a robust model of collective responsibility encompassing all stakeholders involved in the development and deployment of AI technologies. Such a framework promotes responsible and ethical conduct by all parties, with the overarching aim of minimising risk and harm. Developers of artificial intelligence, as well as medical professionals utilizing these technologies, must remain fully aware of their responsibilities. They should receive proper training, comply with ethical standards, and be prepared to assume accountability for any potential adverse outcomes.

Another critical ethical challenge in the application of AI in healthcare is the protection of patient privacy and the confidentiality of medical data. Digital technologies, including electronic health records (EHRs), facilitate the rapid and virtually unlimited replication and dissemination of sensitive information. This amplifies the risk of data being accessed by unauthorised entities, such as government agencies, employers, or insurance companies. Breaches of confidentiality can have numerous adverse consequences for patients, ranging from feelings of shame and stigmatisation to discrimination in employment or unjustified increases in insurance premiums (Glintić and Bezbradica 2025).

Despite the growing integration of AI in healthcare, the fundamental value of the healthcare system continues to be the trust-based relationship between doctors and patients, which rests on mutual respect, empathetic communication, and collaboration. Patients rely on the professional expertise of physicians, while doctors depend on accurate and truthful information from their patients (Goold and Lipkin 1999, 26).

The introduction of AI into medical practice presents an opportunity to redefine the traditional doctor-patient relationship. Moving away from a paternalistic model, participatory medicine is increasingly emphasised, whereby patients actively engage in decision-making and acquire a deeper understanding of their own health status. While this shift offers significant benefits, it also presents challenges in maintaining the delicate balance between technological assistance and the human dimension of care (Floridi and Cowls 2022, 535–545).

The principal challenge for modern medicine lies not only in the effective implementation of AI technologies but also in safeguarding the core values of the medical profession, where clinical experience and

patient relationships remain indispensable. Regardless of technological advancement, direct interaction and mutual trust between doctors and patients are essential for the provision of quality healthcare. Accordingly, artificial intelligence should be regarded solely as a supportive tool that aids physicians in the decision-making process, rather than as an independent entity capable of replacing them. The ultimate responsibility for all medical decisions must rest with the physician, who remains accountable for the outcomes both professionally and ethically.

## CONCLUSION

The integration of artificial intelligence into medical practice represents a pivotal development in the evolution of contemporary healthcare. This transition redefines the traditional doctor-patient relationship, facilitating a shift from a paternalistic model to participatory medicine, and thereby creating new opportunities to enhance the quality of care. AI applications have the potential to substantially reduce the workload of healthcare professionals by automating routine and repetitive tasks, allowing clinicians to focus on complex patient care and improving the overall accessibility of healthcare services.

Nonetheless, the deployment of AI in healthcare raises significant legal and regulatory challenges, particularly concerning data protection, liability for clinical applications, algorithmic oversight, and the mitigation of potential decision-making biases. The development of AI models often relies on sensitive health information, the misuse of which may infringe upon patients' rights to privacy. Moreover, questions of liability remain unresolved when algorithmic systems generate incorrect or harmful clinical recommendations, highlighting the need for clear legal frameworks and robust oversight mechanisms.

Although artificial intelligence has yielded promising results in diagnostics and therapy, particularly in oncology, radiology, and preventive medicine, it has the potential to exacerbate existing social inequalities if developed or deployed without due diligence and responsibility. Biases present in input data can be encoded into algorithmic models, potentially resulting in discriminatory outcomes based on ethnicity, race, nationality, or other personal characteristics. Such consequences may have far-reaching implications, including unequal access to healthcare and potential violations of fundamental human rights (Reddy *et al*. 2020, 491–497).

Accordingly, the development and implementation of AI in healthcare must be guided by ethical, fair, accountable, and transparent principles, underpinned by clearly defined legal frameworks and robust patient protection mechanisms. While artificial intelligence should serve as a supportive tool rather than a replacement for physicians, the role of the clinician must remain central to all aspects of clinical decision-making. In many respects, the growing integration of artificial intelligence in medicine exemplifies the boundless potential of human ingenuity. By harnessing the capabilities of AI, we not only push the frontiers of scientific knowledge but also reaffirm our dedication to the core tenets of medicine: preventing disease, alleviating suffering, and protecting the dignity of human life.

## REFERENCES

Ahn, Jong S, Sangwon Shin, Su-A Yang, Eun K. Park, Ki H. Kim, Soo I. Cho, Chan-Young Ock, and Seokhwi Kim [Ahn *et al.*]. 2023. "Artificial Intelligence in Breast Cancer Diagnosis and Personalized Medicine." *Breast Cancer* 26 (5): 405–435. DOI: 10.4048/jbc.2023.26.e45

Andonović, Stefan. 2020. „Strateško-pravni okvir veštačke inteligencije u uporednom pravu." *Strani pravni život* 64 (3): 111–123.

Annual Report on performed audits and operations of the State Audit Office 2024. 2024. Skopje: State Audit Office. Last Accessed on November 1, 2025. https://dzr.mk/sites/default/files/2025-07/SAO-Annual-report_2024_en.pdf

Ćirić, Jovan. 1991. „Krivično delo nesavesnog lečenja bolesnika." *Zbornik Instituta za kriminološka i sociološka istraživanja* 19 (1–2): 11–109.

Dabić, Dragana. 2025. "European Office for Artificial Intelligence." *European Legislation* 24 (89): 221–238.

Digital Public Administration Factsheets – North Macedonia. 2024. National Interoperability Framework Observatory (NIFO). Last Accessed on November 1, 2025. interoperable-europe.ec.europa.eu/sites/default/files/inline-files/NIFO_2024%20Supporting%20Document_North%20Macedonia_vFINAL.pdf

Đurđević, Nenad. 1997. *Pristanak pacijenta na lečenje.* Kragujevac: Pravni fakultet, Institut za pravne i društvene nauke.

Ethics and governance of artificial intelligence for Health. 2021. WHO guidance. Last Accessed on November 1, 2025. https://iris.who.int/server/api/core/bitstreams/4f2c477c-4b72-4ca1-9a78-a1e73af64e50/content

Floridi, Luciano, and Josh Cowls. 2022. "A Unified Framework of Five Principles for AI in Society." *Applications in Architecture and Urban Design*: 535–545.

Gentile, Francesco, and Natalia Malara. 2024. "Artificial intelligence for cancer screening and surveillance." *ESMO Real World Data and Digital Oncology* 5: 100046.

Glintić, Mirjana, and Bezbradica, Anja. 2025. "Artificial intelligence as a cause of discrimination in insurance law." In *International scientific conference Contemporary challenges in the achievement and protection of human rights*, ed. Duško Čelić, 97–114. Kosovska Mitrovica: University of Priština, Faculty of Law, Institute for criminological and sociological research; Belgrade: Institute for comparative law.

Goold, Dorr, and Mack Jr Lipkin. 1999. "The doctor-patient relationship: challenges, opportunities, and strategies." *Journal of General Internal Medicine* 14 (S26): 26–33. DOI: 10.1046/j.1525-1497.1999.00267

Griffiths, Sarah. 2016. "This AI Software Can Tell If You're at Risk from Cancer before Symptoms Appear." *Şubat* 23: 2019.

Gulshan, Varun, Lily Peng, Marc Coram, Martin Stumpe, Derek Wu, Arunachalam Narayanaswamy, Subhashini Venugopalan, Kasummi Widner, Tom Madams, Jorge Cuadros, Ramasamy Kim, Rajiv Raman, Philip C. Nelson, Jessika L. Mega, and Dare R. Webster [Gulshan *et al*.]. 2016. "Development and Validation of a Deep Learning Algorithm for Detection of Diabetic Retinopathy in Retinal Fundus Photographs." *Journal of the American Medical Association* 316 (22): 2402–2410. DOI: 10.1001/jama.2016.17216

Johnson, Kevin. Wei Q Wei, Dilhan Weeraratne, Mark E. Frisse, Karl Misulis, Kuy Rhee, Juan Zhao, and Jane Snowdon [Johnson *et al*.]. 2021. "Precision Medicine, AI, and the Future of Personalized Health Care." *Clinical and Translational Science* 14 (1): 86–93. DOI: 10.1111/cts.12884

Kačer, Hrvoje, i Blanka Kačer. 2019. „Robotika i umjetna inteligencija u medicini–građanskopravni aspekt odgovornosti za štetu." U *Medicina, pravo i družba globalizacija medicine v 21. stoletju*, ur. Suzana Kraljić, Reberšek Gorišek, Jelka i Vesna Rijavec, 71–89. Maribor: Pravna fakulteta Univerze v Ljubljani.

Kostić, Emilija, Dimitrije Pavlović, and Miroslava Živković. 2019. "Applications of artificial intelligence in medicine and pharmacy." *Acta Medica Medianae* 58 (3): 128–137.

Kraft, Daniel. 2019. "Connected and high-tech: your healthcare future." *National Geographic Hrvatska*: 27–36.

McCarthy, John. 2007. "From here to human level-AI." *Artificial Intelligence* 171 (18): 1174–1182.

Miljuš, Dragan, Snežana Živković-Perišić, i Zorica Božić. 2022. *Maligni tumori u Republici Srbiji*. Beograd: Institut za javno zdravlje Srbije „Dr Milan Jovanović Batut."

Nikolić Popadić, Sofija, i Marta Sjeničić. 2024. "The use of artificial intelligence in healthcare and medicine – legal aspects." *Journal of Ethics and Legal Technologies* 6 (2): 21–39.

Praveen, Phani S., Parvathaneni N. Srinivasu, Jana Shafi, Marcin Wozniak, and Muhammad F. Ijaz [Praveen *et al.*]. 2022. "ResNet-32 and Fast AI for diagnoses of ductal carcinoma from 2D tissue slides." *Scientific Reports* 12 (1): 20804. DOI: 10.1038/s41598-022-25089-2

Prlja, Dragan, Gordana Gasmi, i Vanja Korać. 2021. *Veštačka inteligencija u pravnom sistemu EU*. Beograd: Institut za uporedno pravo.

Radenović, Sandra. 2012. *Bioetika i Medicina*. Novi Sad: Akademska knjiga.

Reddy, Sandeep, Sonia Allan, Simon Coghlan, and Paul Cooper [Reddy *et al*.]. 2020. "A Governance Model for the Application of AI in Health Care." *Journal of the American Medical Informatics Association* 27 (3): 491–497.

Regulation (EU) No 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1–88.

Regulation (EU) No 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act), OJ L 152, 3.6.2022, p. 1–44.

Regulation (EU) No 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), OJ L, 12.7.2024.

Regulation (EU) No 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, OJ L, 5.3.2025.

Saha, Anindo, Joeran S. Bosma, Jasper J. Twilt, Bram van Ginneken, Anders Bjartell, Anwar R. Padhani, David Bonekamp, Geert Villeirs, Georg Salomon, Gianluca Giannarini, Jayashree Kalpathy-Cramer, Jelle Barentsz, Klaus H. Maier-Hein, Mirabela Rusu, Olivier Rouvière, Roderick van den Bergh, Valeria Panebianco, Veeru Kasivisvanathan, Nancy A. Obuchowski, Derya Yakar, Mattijis Elschot, Jeroen Veltman, Jurgen J. Fütterer, Maarten de Rooij, and Henkjan Huisman (PI-CAI consortium) [Saha *et al*.]. 2024. "Artificial intelligence and radiologists in prostate cancer detection on MRI (PI-CAI): an international, paired, non-inferiority, confirmatory study." *The Lancet Oncology* 25 (7): 879–887.

Scharma, Manisha. 2024. "The Impact of AI on Healthcare Jobs: Will Automation Replace Doctors." *American Journal of Data Mining and Knowledge Discovery* 9 (2): 32–35. DOI: 10.11648/j.ajdmkd.20240902.11

Scherer, Matthew U. 2016. "Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies, and Strategies." *Harvard Journal of Law and Technology* 29: 359–362.

Schneeberger, David, Karl Stöger, and Andreas Holzinger. 2020. "The European Legal Framework for Medical AI." In *4*th *International Cross-Domain Conference for Machine Learning and Knowledge Extraction* (CD-MAKE), eds. Elisa Bertino, Wen Gao, Bernhard Steffen, Moti Yung, 209–226. Cham: Springer International Publishing.

Shah, Shahid M, Rizwan A. Khan, Sheeraz Arif, and Unaiza Sajid [Shah *et al*.] 2022. "Artificial intelligence for breast cancer analysis: Trends & directions." *Computers in Biology and Medicine* 142: 105221. DOI: 10.1016/j.compbiomed.2022.105221

Sovilj, Ranko. 2023. „Primena veštačke inteligencije u zdravstvenoj zaštiti: neka pravna pitanja." U *Aktuelnosti medicinskog prava: teorija, praksa i zakonodavstvo 4, okrugli sto,* ur. Hajrija Mujović, 14–17. Beograd: Institut društvenih nauka; Novi Sad: Advokatska komora Vojvodine.

Sovilj, Ranko, and Sanja Stojković-Zlatanović, Sanja. 2023. "Artificial Intelligence in Health Care: Applications, Possible Legal Implications and Challenges of Regulation." In *Regional Law Review*, ed. Mario Reljanović, 223–235. Belgrade: Institute of Comparative Law in Belgrade, University of Pécs: Faculty of Law, University of Ljubljana: Faculty of Law.

Srinivasu, Naga Parvathanen, Jalluri Gnana SivaSai, Muhammad Fazal Ijaz, Akash Kumar Bhoi, Wonjoon Kim, and James Jin Kang [Srinivasu *et al*.] 2021. "Classification of Skin Disease Using Deep Learning

Neural Networks with MobileNet V2 and LSTM." *Sensors* 21 (8): 2852. DOI: 10.3390/s21082852

Stjepanović, Bogdana. 2024. "Leveraging artificial intelligence in ediscovery: enhancing efficiency, accuracy, and ethical considerations." In *Regional Law Review*, eds. Jelena Kostić, Anita Rodina, and Teresa Russo, 179–193. Belgrade: Institute of Comparative Law, University of Pécs: Faculty of Law, University of Ljubljana: Faculty of Law, University of Latvia: Faculty of Law.

Stjepanović, Bogdana. 2025. "Road Towards a Digitally Enhanced Future for Marriage Contract in Serbia." In *Regional Law Review*, ed. Mario Reljanović, 183–193. Belgrade: Institute of Comparative Law, University of Pécs: Faculty of Law, University of Ljubljana: Faculty of Law.

Strategija za razvoj veštačke inteligencije u Republici Srbiji za period 2020–2025 [SRVIRSP 2020–2025], „Službeni glasnik RS", br. 96/2019.

Strategija za razvoj veštačke inteligencije u Republici Srbiji za period 2025–2030 [SRVIRSP 2025–2030], „Službeni glasnik RS", br. 5/2025. Last Accessed on October 30, 2025. nitra.gov.rs/images/vesti/2025/2025-01-10-link/Strategija%20razvoja%20vestacke%20inteligencije%202025-2030.pdf

Vukadinović Marković, Jelena. 2024. „Evropska zdravstvena unija." U *Pravo na pravdu – izazovi savremenog doba*: *Zbornik radova 37. susreta Kopaoničke škole prirodnog prava – Slobodan Perović*, ur. Jelena S. Perović Vujačić, 479–492. Beograd: Kopaonička škola prirodnog prava – Slobodan Perović.

Vukadinović Marković, Jelena, Ivana Radomirović, i Bogdana Stjepanović. 2025. „Sociološki i etički aspekata informisanog pristanka onkološkog pacijenta u pravu Republike Srbije." *Sociološki pregled* 59 (3): 865–888. DOI: 10.5937/socpreg59-5855910.5937/socpreg59-585593

Vulli, Adatsh, Parvathaneni N. Srinivasu, Madipally S. K. Sashank, Jana Shafi, Jaeyoung Choi, and Mahummad F. Ijaz [Vulli *et al*.]. 2022. "Fine-Tuned DenseNet-169 for Breast Cancer Metastasis Prediction Using FastAI and 1-Cycle Policy." *Sensors* 22 (8): 2988. DOI: 10.3390/s22082988

Wohlthat, Anna. 2020. *Artificial intelligence in Healthcare: possibilities and challenges*. Alphen aan den Rijn: Wolters Kluwer Law & Business.

Zaključak o usvajanju etičkih smernica za razvoj, primenu i upotrebu pouzdane i odgovorne veštačke inteligencije [ZUESRPUPOVI], „Službeni glasnik Republike Srbije", br. 23/2023.

Zakon o pravima pacijenata, „Službeni glasnik Republike Srbije", br. 45/2013 i 25/2019.

Закон за заштита на правата на пациентите, „Службен весник на РСМ", бр. 82/2008, 12/2009, 53/2011, и 150/2015.

Закон на заштита на личните податоци, „Службен весник на РСМ", бр. 42/2020, и 294/2021.

Здравковска, Жанета 2025. „Македонски доктори со помош на вештачка интелигенција создаваат модел за предвидување компликации по трансплантација на матични клетки." *Fakulteti.mk.* Последен пристап 29. октомври 2025. www.fakulteti.mk/news/22082025/makedonski-doktori-so-pomosh-na-veshtachka-inteligencija-sozdavaat-model-za-predviduvanje-komplikacii-po-transplantacija-na-matichni-kletki

Камбовски, Игор, и Елена Стојановска. 2024. *Истражување за ефектот на новите технологии, со особен фокус на вештачката интелигенција, врз човековите права на интернет и развивање етички стандарди за заштита на човековите права на интернет при автоматско донесување одлуки.* Скопје: Фондација за интернет и општество Метаморфозис.

Конечен извештај за извршена ревизија на успешност на тема Можност за употреба на вештачка интелигенција во јавниот сектор. 2025. Скопје: Државен завод за ревизија. Последен пристап 1. ноември 2025. https://dzr.mk/sites/default/files/2025-08/KRI_RUS_Vestacka_intelegencija_FINAL.pdf

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# ПРИМЕНА ВЕШТАЧКЕ ИНТЕЛИГЕНЦИЈЕ У ЗДРАВСТВЕНОЈ ЗАШТИТИ: ДИЈАГНОСТИЧКИ ПОТЕНЦИЈАЛИ, ПРАВНИ ОКВИР И ЕТИЧКИ ИЗАЗОВИ[***]

## Резиме

Улога вештачке интелигенције (ВИ) све је израженија у савременом друштву, укључујући и сектор здравствене заштите. Иако је медицина иницијално показивала одређену резервисаност према примени напредних технологија, у новије време бележи се убрзан раст интеграције ВИ у клиничкој пракси, с потенцијалом да темељно трансформише начине дијагностиковања, лечења и предикције болести. Имајући у виду да је борба против малигних болести један од кључних приоритета здравствене политике Европске уније, артикулисан кроз стратешки документ Европски план за борбу против рака (*Europe's Beating Cancer Plan*), овај рад се бави анализом потенцијала ВИ у остваривању циљева поменуте агенде, са посебним освртом на унапређење скрининг програма и развој персонализованих терапијских приступа. Рад је структуриран у три тематске целине. У првом делу се, кроз емпиријски приступ, разматра потенцијал ВИ у клиничком контексту, нарочито у домену унапређења дијагностичке тачности и предиктивне аналитике. Други део фокусиран је на правни оквир примене ВИ

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[***] Рад је резултат међународне сарадње два аутора. Истраживање др Вукадиновић Марковић је настало у оквиру пројекта „Прилагођавање правног оквира друштвеним и технолошким променама са посебним освртом на регулисање вештачке интелигенције” који у 2025. години спроводи Институт за упоредно право уз финансијску подршку Министарства науке, технолошког развоја и иновација (евиденциони број: 451-03-136/2025-03/200049 од 04.02.2025).

у здравственим системима Републике Србије и Републике Северне Македоније, при чему се користи упоредноправна метода. Трећи део посвећен је анализи етичких изазова, као што су заштита приватности пацијената, алгоритамска пристрасност и комплексност остваривања информисаног пристанка у технолошки посредованом медицинском окружењу. Методолошки, рад се ослања претежно на квалитативну анализу правних аката, стручне и научне литературе, док се квантитативни налази интегришу у мери у којој су доступни кроз већ спроведене медицинске студије.

**Кључне речи:** вештачка интелигенција, скрининг програм, персонализовани третман, информисани пристанак пацијента, заштита података пацијента

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