STUDIA PRAWNICZE. Rozprawy i Materiały 2025, nr 1 (36)
STUDIES IN LAW: Research Papers 2025, No. 1 (36)
e-ISSN 2451-0807 • ISSN 1689-8052
DOI: 10.48269/2451-0807-sp-2025-1-08

Piotr Szudejko
PhD, University of Gdańsk
orcid.org/0000-0002-5259-8759
szudejko@legalfactory.pl

Legal and ethical aspects of the use of artificial intelligence tools in healthcare

Introduction

In November 2022, the first tool utilizing language models based on neural networks, known as ChatGPT[1], was made publicly available. Concurrently, artificial intelligence (AI) research was being conducted by several private sector entities, with OpenAI[2] being the first to release a product that, although not devoid of imperfections[3], was sufficiently refined for public use. This brought the AI to the attention of the public, however by that time specialized tools using AI were already developed or even functioning in various areas of human activity, including healthcare[4]. A mere cursory discussion of the significance of this discovery undoubtedly exceeds the

1 A. Azaria, R. Azoulay, S. Reches, *ChatGPT is a remarkable tool – for experts*, "Data Intelligence" 2024, vol. 6, no. 1, pp. 240–243; G. Margas, T. Muras, *Chat GPT 4: Sztuczna inteligencja, czym jest i jak może zmienić nasz świat*, Szczecin 2023, pp. 28–31.

2 A. Azaria, R. Azoulay, S. Reches, *ChatGPT is a remarkable*…, *op. cit*.

3 G. Margas, T. Muras, *Chat GPT 4*…, *op. cit*., pp. 35–36.

4 M. Boden, *Sztuczna inteligencja. Jej natura i przyszłość*, tłum. T. Sieczkowski, Łódź 2020, pp. 13–15.

scope of this paper. Moreover, it can be presumed that its true implications will only become apparent after a longer period of time. One may cautiously hypothesize that the most profound impact will stem from the use of AI tools in education, entertainment, commerce, services – particularly those of an advisory and creative nature – innovative technology development, and healthcare.

At the core of AI lies the use of algorithms, which are a set of actions aimed at solving a specific problem, interpreting data, facilitating machine learning, and making decisions[5]. The primary advantage of AI over a human-executed process is the ability to rapidly analyze data while simultaneously identifying patterns[6]. However, a divergence occurs between the functioning of the algorithm immediately after its creation by humans and its performance after undergoing several iterations of the learning process. This represents a unique paradox, as the functioning AI system becomes its own creator and operates in an increasingly autonomous manner, independent of human intervention. In this article, a stress will be put on legal and ethical consequences of deployment of AI tools in healthcare.

AI in healthcare

In the field of healthcare, AI can primarily be applied to diagnostics, therapy, and healthcare management. The aggregation and analysis of large data sets potentially enable more precise decision-making, minimizing the risk of errors. The IT industry utilizing AI is also expanding in this area, offering solutions that support diagnostic and treatment processes.

Machine learning algorithms have greater capabilities in detecting anomalies during the review of images obtained from X-rays, CT scans, or MRIs[7]. This is primarily due to the ability to analyze large amounts of data, which would be too time-consuming or even

[5] *Algorithm*, britannica.com/science/algorithm [accessed: 4.01.2025].

[6] X.Y. Zhang, C.L. Liu, C.Y. Suen, *Towards robust pattern recognition: A review*, "Proceedings of the IEEE" 2020, vol. 108, no. 6, pp. 894–922.

[7] J. Cytowski, J. Gielecki, A. Gola, *Cyfrowe przetwarzanie obrazów medycznych. Algorytmy. Technologie. Zastosowania*, Warszawa 2008, pp. 109 and n.

impossible for a specialist doctor. Results appear promising, as AI achieves comparable outcomes, for example, in breast cancer detection, to those achieved by traditional methods (human-operated mammography)[8].

Algorithms are used for predicting the future onset of diseases that currently show no symptoms or only exhibit non-specific symptoms. This method involves integrating data from various sources (e.g., genetic tests, lifestyle analysis, diet, statistical data) and developing predictions regarding the occurrence of a specific condition within a given timeframe[9]. It is also possible to identify high-risk groups that are more likely to develop certain diseases. Such actions are currently being implemented both in diagnostics and therapy, examples include tools that support the detection of diabetic retinopathy and breast cancer, developed by DeepMind Technologies Limited[10], tools for analyzing CT scan images (particularly for detecting hemorrhages and pathological changes) created by Aidoc Medical[11], the PathAI system for analyzing histopathological samples[12], and the Tempus Next Oncology, which integrates and

8 N. Houssami, G. Kirkpatrick-Jones, N. Noguchi, C.I. Lee, *Artificial Intelligence (AI) for the early detection of breast cancer: A scoping review to assess AI's potential in breast screening practice*, "Expert Review of Medical Devices" 2019, vol. 16, no. 5, pp. 351–362.

9 K. Wojdan, M. Moniuszko, *Sztuczna inteligencja w medycynie – stan aktualny i wyzwania*, "Nauka" 2022, nr 3, pp. 1–52.

10 K. Arulkumaran, A. Cully, J. Togelius, *AlphaStar: An evolutionary computation perspective*, "Proceedings of the Genetic and Evolutionary Computation Conference Companion" 2019, n. pag.; S.M. McKinney, M. Sieniek, V. Godbole *et al*., *International evaluation of an AI system for breast cancer screening*, "Nature" 2020, no. 577, pp. 89–94.

11 S. Ammari, A.O. Camez, A. Ayobi *et al*., *Contribution of an Artificial Intelligence tool in the detection of incidental pulmonary embolism on oncology assessment scans*, "Life" 2024, vol. 14, no. 11, n. pag.

12 E.A. Rakha, M. Toss, S. Shiino, P. Gamble, R. Jaroensri, C.H. Mermel, P.-H. Cameron Chen, *Current and future applications of artificial intelligence in pathology: A clinical perspective*, "Journal of Clinical Pathology" 2021, vol. 74, no. 7, pp. 409–414; C. McGenity, E.L. Clarke, C. Jennings, G. Matthews, C. Cartlidg, H. Freduah-Agyemang, D.D. Stocken, D. Treanor, *Artificial intelligence in digital pathology: A systematic review and meta-analysis of diagnostic test accuracy*, "npj Digital Medicine" 2024, vol. 7, art. 114.

analyzes genetic and clinical data to personalize cancer treatment[13]. Furthermore, AI is used in telemedicine and patient care, especially where access to a physician is limited. Diagnostic chatbots (e.g., Ada Health[14], Babylon Health[15]) offer such support. AI also plays a significant role in pharmacology, assisting in the research and development of new drugs (e.g., COVID-19 vaccines).

It seems prudent to integrate healthcare AI with the oversight of results conducted by a specialist doctor to minimize the risk of errors and their recurrence in the future. A significant issue arises from both ethical and legal perspectives concerning accountability for potential diagnostic errors, including both false negatives and false positives. This is critical because the diagnosis dictates subsequent actions in the treatment process and can potentially affect its success if unnecessary medical interventions are taken or if necessary interventions are neglected.

Predictions made by AI systems may also be used for non-medical purposes, such as health risk assessments by insurance companies or employers. The implementation of appropriate legal safeguards appears essential, both at the national legislative level and through international regulations, which may be necessary to strengthen the negotiating position towards companies offering AI tools.

In-depth analysis of the health status of patients can be used to personalize the proposed therapy by adapting the methods employed to the individual's health situation, the predicted course of

---

[13] *Tempus introduces its AI-enabled care pathway intelligence platform, Tempus Next*, 16.04.2024, tempus.com/news/tempus-introduces-its-ai-enabled-care-pathway-intelligence-platform-tempus-next [accessed: 4.01.2025].

[14] H. Fraser, D. Crossland, I. Bacher, M. Ranney, R. Madesn, R. Hilliard, *Comparison of diagnostic and triage accuracy of Ada Health and WebMD Symptom Checkers, ChatGPT, and Physicians for Patients in an Emergency Department: Clinical data analysis study*, "JMIR Mhealth Uhealth" 2023, no. 11, n. pag.

[15] A. Baker, Y. Perov, K. Middleton, J. Baxter, D. Mullarkey, D. Sangar, M. Butt, A. DoRosario, S. Johri, *A Comparison of artificial intelligence and human doctors for the purpose of triage and diagnosis*, "Frontiers in Artificial Intelligence" 2020, no. 3, n. pag.; K. Middleton, M. Butt, N. Hammerla, S. Hamblin, K. Mehta, A. Parsa, *Sorting out symptoms: Design and evaluation of the 'babylon check' automated triage system*, arxiv.org/abs/1606.02041 [accessed: 4.01.2025].

the disease, the effectiveness of the treatment, the possibility of side effects, *etc*.[16]

The application of AI tools (including in medicine) can essentially take two forms: soft and hard. In the soft use of AI, the decision-maker bases their reasoning on suggestions obtained from the algorithm, with the degree of AI's influence on the final decision varying depending on the knowledge and experience of the system operator. This person may also, after a form of consultation with the algorithm, make a decision different from the one suggested. In the hard use of AI the human factor is eliminated, and the algorithm provides a ready solution to the problem, which the human (if their involvement is necessary at all) only implements. As a result of this distinction, two separate regimes of responsibility can be proposed. For soft AI use, responsibility for potential medical errors lies with the doctor, whose role is to verify the data from various sources (including from AI-based tools) and make the final decision[17] or also with a healthcare institution hiring such a doctor (organizational fault)[18]. Within the hard AI use, however, the doctor's responsibility is limited to faults in selection (*culpa in eligendo*)[19], while the tool provider bears responsibility for a delict, based on risk[20].

As a tool, AI seems to possess immense potential in healthcare, with its applications encompassing diagnosis, treatment, as well

---

16 S. Patrzyk, A. Woźniacka, *Sztuczna inteligencja w medycynie*, "Umedical Reports" 2022, nr 6, pp. 14–21.

17 A. Chłopecki, *Sztuczna inteligencja – szkice prawnicze i futurologiczne*, Warszawa 2021; L. Bosek, *Perspektywy rozwoju odpowiedzialności cywilnej za inteligentne roboty*, „Forum Prawnicze" 2019, nr 2, p. 5.

18 M. Wałachowska, *Sztuczna inteligencja a zasady odpowiedzialności cywilnej*, [in:] *Prawo sztucznej inteligencji*, red. L. Lai, M. Świerczyński, Warszawa 2020, Legalis.

19 W. Dubis, *Art. 429 KC*, [in:] *Kodeks cywilny. Komentarz*, red. E. Gniewek, P. Machnikowski, Warszawa 2017, pp. 899–901.

20 A. Wolter, *Prawo cywilne. Zarys części ogólnej*, Warszawa 1977, p. 105 and n.; S. Grzybowski, *Prawo cywilne. Zarys części ogólnej*, Warszawa 1974, p. 84 and n.; P. Kaniewski, K. Kowacz, *Odpowiedzialność cywilna za szkody spowodowane funkcjonowaniem sztucznej inteligencji*, "Palestra" 2024, nr 11, pp. 6–33; P. Stylec-Szromek, *Sztuczna inteligencja – prawo, odpowiedzialność, etyka*, "Scientific Papers of Silesian University of Technology. Organization and Management Series" 2018, no. 123, pp. 501–509.

as the development of new medications. Nonetheless, the use of AI tools raises ethical and legal concerns, primarily regarding the protection of patient autonomy and their rights to privacy and fair access to new technologies.

Bioethical issues of using AI tools in medicine

The use of AI tools in medicine involves several ethical issues: the necessity to respect patient rights, especially their autonomy and right to privacy, ensuring fair access to AI-based technology, and the so-called 'black box' problem, which refers to the difficulty or even impossibility of explaining on what basis the AI tool made a diagnosis or selected a particular therapeutic method.

Patient autonomy is based on recognizing their subjectivity as key in the diagnostic and therapeutic process. The patient is both entitled and obliged to make decisions based on information obtained from the doctor or other members of the medical staff. Informed consent can only be given by a competent patient, free from coercion, after receiving full and understandable information about their health status, prognosis, course of treatment, expected effects of the planned intervention, and potential side effects[21]. Only in cases where the patient is unable to make a decision due to their age or health condition can a third party make the decision on their behalf, under permissible paternalism. In Polish law, substitute consent can be given by a statutory representative or a guardianship court, where such consent being referred to as permission[22]. However, the institutions of medical advisors and the principle of substitute judgment have not yet been established[23].

---

[21] P. Łuków, *Zgoda na świadczenie zdrowotne i autonomia pacjenta*, [in:] *Bioetyka*, red. J. Różyńska, W. Chańska, Warszawa 2013, pp. 79–83; M. Boratyńska, P. Konieczniak, *Zasady prawa medycznego*, [in:] *Regulacja prawna czynności medycznych*, red. M. Boratyńska, P. Konieczniak, Warszawa 2019, pp. 55–58.

[22] Art. 32 ust. 2 ustawy z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty [Act of December 5, 1996, on the Professions of Physician and Dentist], Dz.U. [Journal of Laws] 2024, poz. [item] 1287 [consolidated text as of 16.04.2024].

[23] W. Chańska, *Pacjenci niezdolni do wyrażenia zgody*, [in:] *Bioetyka*, *op. cit.*, pp. 103–106.

As mentioned, the use of algorithms in the diagnostic process may lead to difficulties or even the impossibility of explaining exactly how a particular diagnosis was made. Consequently, obtaining the patient's informed consent for the proposed medical intervention (treatment) might be unfeasible. Explaining the reasons for a diagnosis is a crucial element of health information, which forms a condition of informed consent.

The only solution seems to be obtaining a kind of blank consent that covers the use of AI for diagnosis, while also basing the subsequent treatment process on that diagnosis. This would be akin to the consents given for the potential extension of a surgical procedure, where the physician makes decisions based on information gathered during the procedure itself[24]. However, such consent would not possess the attribute of consciousness.

The patient should also have the right to refuse participation in examinations and treatments involving AI. In the case of refusal to undergo AI-based treatment, it would be advisable to ensure that the patient is provided with other opportunities to receive health services, exclusively administered by human personnel. These observations could be generalized by postulating a new patient right – the right to human-provided treatment. The corollary of this right would be the obligation for the healthcare provider to provide care that does not utilize AI tools in any form. The legal basis for such a right would be the refusal of proposed treatment, which is already a well-established principle. As M. Pruski observes, maintaining this right may become increasingly challenging as AI-driven healthcare continues to advance[25]. An unintended consequence of insisting solely on human-based healthcare could be a decline in the quality of services, particularly as AI systems achieve greater

[24] D.K. Harris, R. Zimmermann, *Expanding the scope of surgery: Patient autonomy and consent in the operating room*, "Journal of Clinical Surgery" 2019, vol. 22, no. 2, pp. 85–92; M.J. Clark, E.S. Roberts, *The principle of informed consent and its role in expanding surgical procedures*, "Annals of Surgery" 2020, vol. 272, no. 4, pp. 640–645; R.A. Thompson, J.D. Smith, *Legal and ethical considerations of expanding the scope of a surgical procedure: A review*, "The American Journal of Surgery" 2021, vol. 222, no. 1, pp. 45–52.

[25] M. Pruski, *AI-Enhanced healthcare: Not a new paradigm for informed consent*, "Journal of Bioethical Inquiry" 2024, vol. 21, no. 3, pp. 475–489.

levels of precision and effectiveness. Moreover, it is important to acknowledge that the right to human-based healthcare could potentially impede the progress of AI in this field. Therefore, it may need to be reconsidered or limited to avoid obstructing innovation and development in healthcare. Another issue arising from the use of AI tools in medicine is the need of protection of medical data, concerning both current patients and individuals whose data is included in the datasets utilized by the AI system. To ensure the accuracy of the algorithm, it is essential to provide a sufficient amount of raw data, including health, genetic, and behavioral information[26]. It is necessary to obtain consent for such data usage from the individuals involved. It is not clear whether the currently operating personal data protection system is adequate to ensure the proper level of security for this data. A minimum requirement should be anonymization, meaning the removal of personal data characteristics that allow for the identification of a specific individual[27]. The anonymization process should be irreversible, using computer systems to which the AI tool would not have direct access, to guarantee that the AI cannot access such removed data. Federated learning might also be applied, which avoids transmitting health data to a central server, only sending improvements to the original model that are made locally (e.g., at the level of data processed within a healthcare facility)[28].

Additionally, data should be adequately protected against unauthorized access and interference by both third parties and other AI systems. Accessing health-related information, as well as genetic predispositions to certain diseases, could lead to discrimination in the workplace or refusal to offer health insurance contracts.

---

[26] R.M. Rasmussen, *What huge volume of data are required for smart AI*, ibm.com/blogs/nordic-msp/what-huge-volume-of-data-are-required-for-smart-ai [accessed: 4.01.2025].

[27] I. Olatunji, J. Rauch, M. Katzensteiner, M. Khosia, *A review of anonymization for healthcare data*, "Big Data" 2022, vol. 10, no. 2, pp. 169–184.

[28] T. Li, A.K. Sahu, A. Talwalkar, V. Smith, *Federated learning: challenges, methods, and future directions*, "IEEE Signal Processing Magazine" 2020, vol. 37, no. 3, pp. 50–70.

An essential element to safeguard the autonomy of patients in the use of data in the machine learning process is the transparency of the process, which includes providing the patient with clear information about how and for what purpose their data, including health data, will be processed, what safeguards will be applied, whether it is possible to withdraw consent later, and how personal data will be removed. It should also address whether unauthorized individuals can access the processed data and the potential consequences of such access, *etc*. Only complete, understandable information can ensure respect for the patient's autonomy and enable the patient to give informed consent for the use of their health data.

The use of AI tools, like any advanced technology, requires efforts to ensure equal access. Digital exclusion[29] in healthcare can affect, among others, people who are less wealthy, older, or from smaller communities where access to medical services is already an issue, even with traditional methods. This problem may be particularly prevalent in developing countries, where there may not be sufficient funds to build the necessary infrastructure or acquire licenses to enable the full use of AI systems. One possible solution is to apply preferential licensing fees for developing countries. Another challenge facing AI system developers is ensuring that the algorithm's operation does not lead to discrimination, especially based on gender, ethnicity, or social and economic status[30]. To prevent the marginalization of specific groups and individuals, it is necessary to provide comprehensive data in the algorithm's learning process and ensure equal access to the tools.

The last issue that should be addressed in this section is the so-called 'black box' problem. This issue arises due to the fact that after the deployment of an AI algorithm, its further development may not be fully understandable even to its creators, and even less so for ordinary users[31]. To some extent, this phenomenon can be

[29] E. Inglot-Brzęk, *Brak dostępu do Internetu jako wskaźnik wykluczenia społecznego*, "Nierówności Społeczne a Wzrost Gospodarczy" 2011, nr 19, pp. 374–385.

[30] P. Mering, *Wpływ sztucznej inteligencji na dyskryminację rasową – ujęcie prawne*, "Ad Astra" 2022, nr 6, pp. 10–11, 18–19.

[31] K. Wojdan, M. Moniuszko, *Sztuczna inteligencja*…, *op. cit*., p. 44.

countered by tools like 'explainable AI' (XAI), which aim to present decision-making processes in a more transparent way[32]. Observing the operation of individual tools is necessarily limited to analyzing the results they provide, such as the accuracy of diagnoses or predictions of future health issues. Even a positive assessment of a tool's effectiveness may not provide the information necessary to understand how the solution was derived. The lack of a full understanding of the AI algorithm by the doctor significantly limits the possibility of the patient understanding it, which in turn impairs the patient's ability to give informed consent. One of the primary duties of a doctor is continuous professional development and the use of the latest medical advancements[33], so it can be argued that there is an obligation for doctors to acquire and expand their knowledge in the field of AI tools.

For its importance, this ethical obligation should be achievable, lest it becomes a pharisaical morality. Since even AI creators sometimes struggle to explain how their creations work, it would be unreasonable to expect it from doctors, who do not professionally create algorithms. However, the question arises: is it permissible for a doctor to use a tool whose operation they do not fully understand or cannot explain? It seems the answer is affirmative. A doctor does not need to know all aspects of a new tool's functioning to use it effectively and ethically. It is sufficient to understand the general principles of its' operation, application, purpose, and potential side effects to patient's health.

An opposite conclusion would lead to absurdity, a doctor would not be able to apply a new technological solution until they acquire detailed knowledge of how it functions. Until that point, the doctor would have to use an older tool, which might be less effective, to the detriment of patients. However, there is no doubt that limited knowledge in this area can lead to a higher percentage of patients refusing AI-assisted therapy.

---

[32] A.M. Leventi-Peetz, T. Östreich, W. Lennartz, K. Weber, *Scope and sense of explainability for AI-systems*, [in:] *Intelligent systems and applications*, ed. K. Arai, Cham 2022, pp. 291–308.

[33] M. Boratyńska, P. Konieczniak, *Zasady prawa medycznego*…, *op. cit*., p. 43.

Legal aspects of AI use in medicine

A key issue regarding the use of AI tools in medicine is the development of an appropriate regulatory framework that allows for the continued advancement of AI technologies while ensuring proper protection of patient rights. Central to these regulations should be the determination of civil and criminal liability for medical errors resulting from the use of AI tools, as well as the establishment of quality assurance measures for AI systems through certification before their deployment in healthcare.

The introduction of regulations governing AI in medicine appears necessary due to the rapid development of this technology and the need to protect patients, doctors and healthcare providers from associated risks. Furthermore, the creation of international, harmonized regulations that ensure uniform standards is essential.

Currently, national legal provisions do not directly address the use of AI and other digital technologies in medicine. General Data Protection Regulation 2016/679 (GDPR) finds a limited application in the context of personal data processing, including machine processing.

The GDPR regulates the acceptable ways of processing personal data, including automated processing. The basic principle of personal data processing is the consent of the individual whose data is being processed (Art. 6(1)(a) GDPR)[34]. Consent, as defined in Art. 4(11) of the GDPR, is the voluntary, specific, informed, and unambiguous indication of a person's will through a declaration or a clear action, granting permission for their personal data to be processed. As a rule, it is therefore not permissible to process data based on implied or tacit consent (through inaction), especially healthcare data, considered sensitive[35]. This creates challenges in acquiring sufficiently large sets of health data, which are necessary for the proper functioning of both diagnostic and predictive algorithms. Obtaining consent for data processing by algorithms requires providing patients with information about how and to what extent their data

[34] D. Lubasz, *Ochrona danych osobowych*, Warszawa 2020, pp. 121–124.

[35] *Ibidem*, pp. 83–84.

will be processed, which may be complicated by the previously discussed 'black box' problem.

An attempt to regulate the use of AI was made in the form of European Parliament and Council Regulation (EU) 2024/1689 of June 13, 2024, on establishing harmonized rules for artificial intelligence and amending several regulations and directives (AI Act)[36]. The aim of this regulation is to implement unified rules for the use of AI tools across various sectors, including healthcare. One of the main provisions is the classification of AI systems based on their assessed risk level, which determines the regulatory scope (art. 6 of the Act). According to paragraph 2 of this article, high-risk systems are those listed in Annex III to the AI Act. However, only points 5(a) and 5(c) of Annex III directly relate to AI systems used in healthcare, while previously proposed references to health systems (point 5(b) and point 6) were not adopted in the final version of the regulation.

According to point 5(a) of Annex III, systems used to qualify individuals for basic public services, including healthcare, are considered high-risk. Similarly, point 5(c) categorizes systems used to assess risk and determine health and life insurance premiums as high-risk.

As a result, some medical algorithms are not classified as high-risk technology, meaning they are not subject to the stringent regulations outlined in the AI Act. There is an urgent need to review this regulation and recognize AI systems used in medicine as high-risk. There should be no doubt that tools used for diagnosis, prediction, and recommending treatment or preventive actions can affect human health, and ultimately, the length and quality of life. This is especially true in the case of 'hard AI' usage models, where the AI makes decisions, and the human merely implements the proposed solutions.

[36] 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, Official Journal of the European Union, L 1689, 12.07.2024.

Another attempt to regulate the liability resulting from the use of AI was made by the European Commission in 2022, when Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence[37] was proposed.

The draft pertains to fault-based liability (article 1(2)) and incorporates a range of provisions designed to strengthen the position of the plaintiff seeking compensation. For instance, pursuant to article 3(1) of the directive, at the plaintiff's request, the court may compel the defendant to disclose evidence in their possession, under penalty of deeming as proven the facts that such evidence was intended to substantiate. Furthermore, article 4(1) of the draft directive establishes a presumption of causality between the defendant's fault and the outcome achieved (or not achieved) by the artificial intelligence system. These adopted measures thus shift fault-based liability towards a framework resembling strict liability. However, it should be noted that the discussed regulation is planned only for AI systems considered a high risk, so may have a limited impact on healthcare.

An important issue resulting from the use of AI tools in medicine is determining responsibility for the diagnostic and therapeutic process, particularly in the case of errors caused by the algorithm's actions. This will concern civil liability (compensatory responsibility), criminal liability, and disciplinary responsibility. In the current models of civil liability, the doctor or other medical personnel, as well as the healthcare institution employing them, are responsible for the consequences of their decisions and actions. Criminal and disciplinary responsibility is more individualized, requiring the assignment of an offense to a specific individual[38]. Furthermore, liability for such offenses depends on the presence of fault by the perpetrator[39].

---

[37] Proposal for a directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive).

[38] M. Budyn-Kulik, *Art. 9*, [in:] *Kodeks karny. Komentarz*, red. M. Mozgawa, Warszawa 2017, pp. 42–47.

[39] Art. 8 i 9 ustawy z dnia 6 czerwca 1997 r. – Kodeks karny, Dz.U. 2024, poz. 17.

The responsibility of medical professionals will differ depending on the adopted model of AI usage: soft or hard. In the soft AI usage model, responsibility will rest with the person making the decision based on the AI system's suggestion, as it is possible to completely disregard the algorithm's response. The hard AI usage model excludes (or significantly limits) human involvement, with their role limited to executing the decision on diagnosis and treatment, so the scope of the operator's responsibility should be lesser than in the soft AI usage model.

AI systems can make automated decisions, leading to the issue of the 'black box'. A doctor may find it difficult to understand why a particular solution is proposed, making it virtually impossible to verify the correctness of the algorithm's operation in such cases. One proposal is to divide civil liability for an incorrect diagnosis and treatment between the treating physician, the entity that introduced the AI tool to the market, and the algorithm's creators, in a model of layered responsibility[40]. In practice, however, it may be difficult to determine who the actual creator of the algorithm is, as often the development involves a team working in two main areas: algorithm creation and testing. Testing involves reviewing the responses provided by the algorithm and assessing whether they are correct or incorrect. Assigning responsibility to a specific individual thus seems very challenging. Moreover, explaining how an error occurred may not be possible. Therefore, a more effective solution seems to be assigning joint civil responsibility to the doctor (fault-based) and the entity introducing the AI tool to the market (risk-based), with the possibility for that entity to seek compensation from the algorithm's creators through recourse.

In the case of criminal and disciplinary responsibility regimes, liability will still rest solely with the doctor, though they will have the opportunity to defend themselves by demonstrating that due diligence was exercised in applying the AI tool and verifying the solutions proposed by it. This updates the previously discussed

[40] D. Liu, S. Kumar, *Legal liability for AI systems: The importance of multi-layered accountability*, "Law, Innovation, and Technology" 2020, no. 12(1), pp. 48–63.

obligation for medical professionals to continuously improve their knowledge.

The creator of the AI tool could also be criminally liable for a medical error caused by their tool, but only if they can be proven to have introduced the error into the tool, resulting in its malfunction.

An essential element of the system for protecting patients' rights should be the proper certification of AI tools in medicine, both before market introduction and periodically during their use. This is particularly important because AI tools can and should evolve even after implementation. This is justified by the changing level of knowledge, potential errors, and the need to adapt the tool to new regulations and requirements. The testing and recertification periods should be adjusted to the extent of this evolution, and it may be necessary to introduce stricter certification rules than for other tools used in medicine.

Practical problems in using AI tools in medicine

Despite the relatively limited application of AI in medicine, these tools already create situations that highlight difficulties arising from the elimination of human decision-making. To fully present the opportunities and risks associated with using algorithms, it is important to discuss identified practical problems, representing main topics discussed and attempt to draw broader conclusions.

Google DeepMind provides predictive tools for early-stage disease detection based on images obtained from traditional devices such as X-rays, CT scans, or retinal images. One of the projects, executed in collaboration with Royal Free NHS Trust, analyzed data regarding kidney function to detect damage. In 2017, it was revealed that DeepMind accessed NHS patient medical data without their explicit prior consent. The data was used only for research purposes and was not disclosed, but the algorithm's actions were deemed to violate patients' privacy due to insufficient safeguards implemented by the responsible entity[41].

[41] S.G. Smith, *Privacy and artificial intelligence: Challenges for protecting health information in a new era*, "BMC Medical Ethics" 2021, vol. 22, no. 1, pp. 1–13;

IBM Watson for Oncology uses AI algorithms to support decision-making in selecting oncology treatments. Watson analyzes patient data, including medical history and genetic test results, and then proposes personalized therapeutic recommendations based on available guidelines and medical literature. However, despite ambitious goals, experts found that Watson for Oncology made incorrect interpretations of the data, resulting in inaccurate recommendations that did not align with current clinical guidelines[42]. This issue arose from limited access to local medical data and differences in healthcare standards occurring between countries.

Even more serious consequences for patient health have occurred with the use of medical chatbots (such as Ada Health or Babylon Health). These tools conduct preliminary diagnoses based on data entered by the patients themselves[43]. In addition to providing medical advice on diagnosis and next steps, they are also intended for health education. However, the use of chatbots carries significant risks of incorrect diagnoses or providing the wrong suggestions for further action. Part of the problem is that patients may present inaccurate or incomplete data about themselves. Incorrect diagnoses can delay obtaining necessary medical help. For instance, in a 2019 case, the Babylon Health chatbot suggested that a patient with symptoms of a heart attack might be suffering from a mere indigestion[44].

Therefore, chatbots should be used cautiously, with proper information of their limitations, provided to the users. It may also be

J. Powles, H. Hodson, *Google DeepMind and healthcare in an age of algorithms*, "Digital Medicine" 2017, no. 1, pp. 1–3.

42 C. Ross, I. Swetlitz, *IBM's Watson supercomputer recommended 'unsafe and incorrect' treatments for cancer patients*, 25.07.2018, statnews.com/2018/07/25/ibm-watson-recommended-unsafe-incorrect-treatments [accessed: 4.01.2025].

43 C. Schulz, D. Juric, J. Shamdasani, M. Coste, S. Wartak, A. Savkov, N. Hammerla, M. Khodadadi, *Babylon health's medical knowledge graph: Why, what, and how*, "CEUR Workshop Proceedings" 2018, vol. 2849, pp. 121–130.

44 S. Bradley, *Bad bots: How should doctors respond to untested technologies?*, "The British Journal of General Practice: The Journal of the Royal College of General Practitioners" 2019, vol. 69, no. 683, p. 297.

necessary to exclude their use for symptoms that could indicate a life-threatening situation.

As can be seen from this brief analysis of practical issues related to the use of AI tools in medicine, there is a need to develop consistent standards regulating the acceptability and manner of algorithm use. These standards should primarily focus on privacy protection, including obtaining patient consent, safeguarding users from the consequences of incorrect diagnoses or therapeutic suggestions, and implementing uniform liability rules for entities introducing AI solutions to the medical services market.

Conclusion

The application of artificial intelligence tools in medicine holds significant potential, primarily due to AI's unparalleled ability to aggregate, analyze large datasets, and detect patterns compared to humans. This translates into improved diagnostics and treatment processes. AI also enables the prediction of future diseases that may currently be undetectable, as well as personalized treatment plans. In addition to improving efficiency, the potential outcome of using AI tools in medicine could be a reduction of diagnostic and treatment costs with widespread implementation.

At the same time, entirely new ethical and legal challenges arise from these solutions. Existing legal frameworks only partially address the demands associated with AI technology, including in the legal domain. A key regulation at the European Union level is Regulation (EU) 2024/1689, but there is a need for more detailed legislative solutions addressing practical issues related to patient rights protection. There is also a call for urgently aligning the aforementioned solutions with AI tools used in healthcare by recognizing them as high-risk systems.

One of the most significant challenges related to the use of AI tools is the need to preserve patient autonomy. Decision-making in medical matters by algorithms should be balanced by the patient's right to refuse such solutions and to limit medical procedures to those that can be provided by human healthcare personnel.

Another crucial aspect of implementing AI tools in healthcare is protecting patient privacy and personal data. There may be a conflict between the need to provide algorithms with sufficient medical data required for efficient machine learning and the patient's right for their medical data to be used solely for their personal health needs. Any other use, including scientific purposes, should be exceptional and subject to separate informed consent by the patient.

Similar to other modern solutions, AI tools are currently a scarce resource, so it is essential to ensure equal access to this technology. During the development of solutions, it is also necessary to consider diverse needs and conditions, including those based on the patient's ethnic origin, age, or existing health conditions. Entities deploying AI systems in healthcare should actively counter digital exclusion in medical services provided using AI tools. It will also be crucial to engage the state and healthcare funding bodies in building appropriate infrastructure.

It is also advisable to propose legal solutions that will clearly define responsibility for potential errors in diagnosis or treatment caused by faulty algorithm performance. It is crucial to specify who and to what extent is responsible for such errors: the attending physician, the algorithm creator, or the entity introducing the algorithm to the healthcare market. Regardless of which model of responsibility is adopted, from the perspective of patient rights protection, it is appropriate to implement uniform solutions on an international scale.

The proposed new subjective right – the right to treatment by a human – has the potential to become a significant addition to the catalogue of patients' rights. However, it may also, as a consequence, impede the development of AI tools.

References

Legal acts

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, Official Journal of the European Union, L 1689, 12.07.2024.
Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty [Act of December 5, 1996, on the Professions of Physician and Dentist], Dz.U. [Journal of Laws] 2024, poz. [item] 1287 [consolidated text as of 16.04.2024].
Ustawa z dnia 6 czerwca 1997 r. – Kodeks karny [Act of June 6, 1997 – Polish Penal Code], Dz.U. [Journal of Laws] 2024, poz. [item] 17.

Literature

Algorithm, britannica.com/science/algorithm [accessed: 4.01.2025].
Ammari S., Camez A.O., Ayobi A. *et al*., *Contribution of an Artificial Intelligence tool in the detection of incidental pulmonary embolism on oncology assessment scans*, "Life" 2024, vol. 14, no. 11, n. pag.
Arulkumaran K., Cully A., Togelius J., *AlphaStar: An evolutionary computation perspective*, "Proceedings of the Genetic and Evolutionary Computation Conference Companion" 2019, n. pag.
Azaria A., Azoulay R., Reches S., *ChatGPT is a remarkable tool – for experts*, "Data Intelligence" 2024, vol. 6, no. 1, pp. 240–243.
Baker Y., Perov Y., Middleton K., Baxter J., Mullarkey D., Sangar D., Butt M., DoRosario A., Johri S., *A comparison of artificial intelligence and human doctors for the purpose of triage and diagnosis*, "Frontiers in Artificial Intelligence" 2020, no. 3, n. pag.
Boden M., *Sztuczna inteligencja. Jej natura i przyszłość*, tłum. T. Sieczkowski, Łódź 2020, pp. 13–15.
Boratyńska M., Konieczniak P., *Zasady prawa medycznego*, [in:] *Regulacja prawna czynności medycznych*, red. M. Boratyńska, P. Konieczniak, Warszawa 2019, pp. 55–58.
Bosek L., *Perspektywy rozwoju odpowiedzialności cywilnej za inteligentne roboty*, "Forum Prawnicze" 2019, nr 2, pp. 3–17.
Bradley S., *Bad bots: How should doctors respond to untested technologies?*, "The British Journal of General Practice: The Journal of the Royal College of General Practitioners" 2019, vol. 69, no. 683, p. 297.
Budyn-Kulik M., *Art. 9*, [in:] *Kodeks karny. Komentarz*, red. M. Mozgawa, Warszawa 2017, pp. 42–47.
Chańska W., *Pacjenci niezdolni do wyrażenia zgody*, [in:] *Bioetyka*, red. J. Różyńska, W. Chańska, Warszawa 2013, pp. 103–106.
Chłopecki S., *Sztuczna inteligencja – szkice prawnicze i futurologiczne*, Warszawa 2021.
Clark M.J., Roberts E.S., *The principle of informed consent and its role in expanding surgical procedures*, "Annals of Surgery" 2020, vol. 272, no. 4, pp. 640–645.

Cytowski J., Gielecki J., Gola A., *Cyfrowe przetwarzanie obrazów medycznych. Algorytmy. Technologie. Zastosowania*, Warszawa 2008.

Dubis W., *Art. 429 KC*, [in:] *Kodeks cywilny. Komentarz*, red. E. Gniewek, P. Machnikowski, Warszawa 2017, pp. 899–901.

Fraser H., Crossland D., Bacher I., Ranney M., Madsen R., Hilliard R., *Comparison of diagnostic and triage accuracy of Ada Health and WebMD Symptom Checkers, ChatGPT, and Physicians for Patients in an Emergency Department: Clinical data analysis study*, "JMIR Mhealth Uhealth" 2023, no. 11, n. pag.

Grzybowski S., *Prawo cywilne. Zarys części ogólnej*, Warszawa 1974.

Harris D.K., Zimmermann R., *Expanding the scope of surgery: Patient autonomy and consent in the operating room*, "Journal of Clinical Surgery" 2019, vol. 22, no. 2, pp. 85–92.

Houssami N., Kirkpatrick-Jones G., Noguchi N., Lee C.I., *Artificial Intelligence (AI) for the early detection of breast cancer: A scoping review to assess AI's potential in breast screening practice*, "Expert Review of Medical Devices" 2019, vol. 16, no. 5, pp. 351–362.

Inglot-Brzęk E., *Brak dostępu do Internetu jako wskaźnik wykluczenia społecznego*, "Nierówności Społeczne a Wzrost Gospodarczy" 2011, nr 19, pp. 374–385.

Kaniewski P., Kowacz K., *Odpowiedzialność cywilna za szkody spowodowane funkcjonowaniem sztucznej inteligencji*, "Palestra" 2024, nr 11, pp. 6–33.

Leventi-Peetz A.M., Östreich T., Lennartz W., Weber K., *Scope and sense of explainability for AI-systems*, [in:] *Intelligent systems and applications*, ed. K. Arai, Cham 2022, pp. 291–308.

Li T., Sahu A.K., Talwalkar A., Smith V., *Federated learning: challenges, methods, and future directions*, "IEEE Signal Processing Magazine" 2020, vol. 37, no. 3, pp. 50–70.

Liu D., Kumar S., *Legal liability for AI systems: The importance of multi-layered accountability*, "Law, Innovation, and Technology" 2020, no. 12(1), pp. 48–63.

Lubasz D., *Ochrona danych osobowych*, Warszawa 2020.

Łuków P., *Zgoda na świadczenie zdrowotne i autonomia pacjenta*, [in:] *Bioetyka*, red. J. Różyńska, W. Chańska, Warszawa 2013, pp. 79–83.

Margas G., Muras T., *Chat GPT 4: Sztuczna inteligencja, czym jest i jak może zmienić nasz świat*, Szczecin 2023.

McGenity S., Clarke E.L., Jennings C., Matthews G., Cartlidge C., Freduah-Agyemang H., Stocken D.D., Treanor D., *Artificial intelligence in digital pathology: A systematic review and meta-analysis of diagnostic test accuracy*, "npj Digital Medicine" 2024, vol. 7, art. 114.

McKinney S.M., Sieniek M., Godbole V. *et al*., *International evaluation of an AI system for breast cancer screening*, "Nature" 2020, no. 577, pp. 89–94.

Mering P., *Wpływ sztucznej inteligencji na dyskryminację rasową – ujęcie prawne*, "Ad Astra" 2022, nr 6, pp. 8–23.

Middleton K., Butt M., Hammerla N., Hamblin S., Mehta K., Parsa A., *Sorting out symptoms: Design and evaluation of the 'babylon check' automated triage system*, arxiv.org/abs/1606.02041 [accessed: 4.01.2025].

Olatunji I.E., Rauch J., Katzensteiner M., Khosia M., *A review of anonymization for healthcare data*, "Big Data" 2022, vol. 10, no. 2, pp. 169–184.

Patrzyk S., Woźniacka A., *Sztuczna inteligencja w medycynie*, "Umedical Reports" 2022, nr 6, pp. 14–21.

Powles J., Hodson H., *Google DeepMind and healthcare in an age of algorithms*, "Digital Medicine" 2017, no. 1, pp. 1–3.

Pruski M., *AI-Enhanced healthcare: Not a new paradigm for informed consent*, "Journal of Bioethical Inquiry" 2024, vol. 21, no. 3, pp. 475–489.

Rakha E.A., Toss M., Shiino S., Gamble P., Jaroensri R., Mermel C.H., Cameron Chen P.-H., *Current and future applications of artificial intelligence in pathology: A clinical perspective*, "Journal of Clinical Pathology" 2021, vol. 74, no. 7, pp. 409–414.

Rasmussen R.M., *What huge volume of data are required for smart AI*, ibm.com/blogs/nordic-msp/what-huge-volume-of-data-are-required-for-smart-ai [accessed: 4.01.2025].

Ross C., Swetlitz I., *IBM's Watson supercomputer recommended 'unsafe and incorrect' treatments for cancer patients*, 25.07.2018, statnews.com/2018/07/25/ibm-watson-recommended-unsafe-incorrect-treatments [accessed: 4.01.2025].

Schulz C., Juric D., Shamdasani J., Coste M., Wartak S., Savkov A., Hammerla N., Khodadadi M., *Babylon health's medical knowledge graph: Why, what, and how*, "CEUR Workshop Proceedings" 2018, vol. 2849, pp. 121–130.

Smith S.G., *Privacy and artificial intelligence: Challenges for protecting health information in a new era*, "BMC Medical Ethics" 2021, vol. 22, no. 1, pp. 1–13.

Stylec-Szromek P., *Sztuczna inteligencja – prawo, odpowiedzialność, etyka*, "Scientific Papers of Silesian University of Technology. Organization and Management Series" 2018, no. 123, pp. 501–509.

Tempus introduces its AI-enabled care pathway intelligence platform, 16.04.2024, tempus.com/news/tempus-introduces-its-ai-enabled-care-pathway-intelligence-platform-tempus-next [accessed: 4.01.2025].

Thompson R.A., Smith J.D., *Legal and ethical considerations of expanding the scope of a surgical procedure: A review*, "The American Journal of Surgery" 2021, vol. 222, no. 1, pp. 45–52.

Wałachowska M., *Sztuczna inteligencja a zasady odpowiedzialności cywilnej*, [in:] *Prawo sztucznej inteligencji*, red. L. Lai, M. Świerczyński, Warszawa 2020, Legalis.
Wojdan K., Moniuszko M., *Sztuczna inteligencja w medycynie – stan aktualny i wyzwania*, "Nauka" 2022, nr 3, pp. 1–52.
Wolter A., *Prawo cywilne. Zarys części ogólnej*, Warszawa 1977.
Zhang X.Y., Liu C.L., Suen C.Y., *Towards robust pattern recognition: A review*, "Proceedings of the IEEE" 2020, vol. 108, no. 6, pp. 894–922.

Abstract
Legal and ethical aspects of the use of artificial intelligence tools in healthcare

The use of artificial intelligence in healthcare offers unprecedented opportunities of development in diagnostics and treatment. AI's ability to aggregate and analyze large datasets significantly improves diagnostic accuracy and predictive capabilities, yet raises concerns about patient autonomy, data privacy, and equitable access. The 'black box' problem and the risk of potential errors in diagnosis or treatment further complicate AI usage in medical practice. Existing regulations, such as the EU AI Act, provide foundational governance but require refinement to address specific challenges of healthcare. This study advocates for harmonized international standards, robust data protection frameworks. A new patients' right to human-provided healthcare is also proposed.
Key words: AI, healthcare, patient's autonomy, right to human-provided healthcare