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Julia Stanek
Associate Professor, Andrzej Frycz Modrzewski Krakow University
orcid.org/0000-0001-8022-2196
jstanek@uafm.edu.pl

Medical artificial intelligence and informed consent

The integration of artificial intelligence (AI) into healthcare systems has the potential to improve systems and increase the availability and quality of medical services. However, this integration raises significant ethical and legal concerns, particularly in relation to patients' rights, especially their right to consent to healthcare. Both national and international regulations emphasise that all medical actions must be conducted with respect for the patient's informed and voluntary will. The implementation of these principles into clinical practice is essential for building trust in the patient–doctor relationship and ensuring the delivery of high-quality healthcare. It is crucial to recognise the significance of the patient's right to consent to medical services in ensuring the protection of fundamental principles of dignity, freedom, and autonomy within the healthcare system.

Patient's right to consent

The right of patients to consent to heath care services or treatment has been addressed in a range of international legal conventions and instruments, which serve as an important complement to

national regulations[1]. For instance, Article 8 of the European Convention on Human Rights[2], which guarantees everyone the right to respect for private and family life, or Article 5 of the Oviedo Convention[3], which underscores the importance of informed consent, stating that

> an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

Within the domain of healthcare, these provisions require that all medical interventions be in accordance with the patient's will and respect their autonomy. It is asserted that any intervention pertaining to the domain of health must be undertaken solely with the prior, unambiguous, and informed consent of the individual concerned. The necessity to provide patients with comprehensive information regarding the nature of the proposed treatment, the potential risks involved, and the available alternatives is thereby emphasised. By codifying the principles of informed, voluntary, and documented consent, Polish regulations align with international standards and ensure the ethical delivery of medical services.

In Poland, this right is codified in several legal instruments, which collectively ensure that medical services are provided with respect for the dignity and self-determination of individuals. Firstly,

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1 See: Universal Declaration on Bioethics and Human Rights, adopted by UNESCO, SHS/EST/BIO/06/1, SHS.2006/WS/14, Article 6(1). The Declaration states that: "Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice".

2 Council of Europe, European Convention on Human Rights (adopted 4 November 1950, entered into force 3 September 1953), European Treaty Series, No 5.

3 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, European Treaty Series, No. 164, Oviedo, 4.4.1997.

it is important to consider the provisions of the Constitution of the Republic of Poland (Constitution)[4], which define the fundamental principles of the protection of individual rights, including the right to consent to the health services. Key provisions in this regard include Article 41 of the Constitution, which guarantees everyone's personal inviolability and personal freedom. This provision is related to the issue of patient autonomy and their right to decide on medical interventions performed on their body[5]. Furthermore, Article 47 of the Constitution ensures the right to protection of one's private and family life, honor, and reputation, as well as the right to make decisions about one's personal life. In the context of medical care, this signifies that patients are entitled to make informed decisions regarding their health and the treatment they receive[6]. Additionally, it is worth noting that Article 30 of the Constitution recognizes the inherent and inalienable dignity of the person as the source of all human rights and freedoms. This provision underpins the principle of informed consent by affirming the autonomy and moral agency of each individual in decisions concerning their own body and health. Furthermore, Article 68 guarantees the right to the protection of health and obliges public authorities to ensure equal access to healthcare services, particularly for vulnerable groups. Considered together, these constitutional norms establish both the right to receive medical care and the right to make autonomous, informed choices regarding such care, including the right to accept or refuse treatment.

The general principles established in the Constitution have been specified and clarified in a series of normative acts that

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4 Konstytucja Rzeczypospolitej Polskiej z dnia 2 kwietnia 1997 r. [Constitution of the Republic of Poland (adopted 2 April 1997)], Dz.U. [Journal of Laws] 1997, nr [no.] 78, poz. [item] 483.

5 W. Brzozowski, *Prawa pacjenta w ujęciu konstytucyjnym*, [in:] *Pojęcie, źródła i zakres prawa medycznego*, red. R. Kubiak, L. Kubicki, E. Zielińska, "System Prawa Medycznego", t. 1, Warszawa 2018, LEX/el.

6 J. Różyńska, *Konstytucja jako źródło norm prawa medycznego*, [in:] *Pojęcie, źródła i zakres prawa medycznego*, *op. cit.*; L. Bosek, *Źródła prawa medycznego*, [in:] *Instytucje prawa medycznego*, red. M. Safjan, L. Bosek, "System Prawa Medycznego", t. 1, Warszawa 2017.

have statutory rank. The main regulations include the Act on the Professions of Physician and Dentist[7], the Act on Patient's Rights and the Patient's Rights Ombudsman (Patients' Rights Act)[8], and the Code of Medical Ethics (KEL)[9]. The aforementioned corpus of legislation stipulates that healthcare professionals must prioritise patients' autonomy and their involvement in the decision-making process regarding their health[10]. These regulations serve to strengthen the patient-physician relationship through mutual respect and understanding, ensure that medical practitioners adhere to legal and ethical standards, and provide patients with the necessary tools to make informed decisions about their health and well-being. The legal framework stipulates a series of criteria that, if fulfilled, grant patient consent validation and legality:

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7 Ustawa z dnia 5 grudnia 1996 r. o zawodzie 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 26.08.2024)]. Articles 32 to 35 of the Act on the Professions of Physician and Dentist establish detailed provisions for obtaining patient consent prior to any medical intervention.

8 Ustawa z dnia 6 listopada 2008 r. o prawach pacjenta i Rzeczniku Praw Pacjenta [Act of November 6, 2008, on Patients' Rights and the Patient's Rights Ombudsman], Dz.U. [Journal of Laws] 2024, poz. [item] 581 [consolidated text as of 16.04.2024]. Chapter 5 [articles 15–19] of the Act on Patient's Rights and the Patient's Rights Ombudsman specifically addresses the patient's right to consent to medical services.

9 Kodeks etyki lekarskiej [Code of Medical Ethics], nil.org.pl/uploaded_images/1723037323_kel-2305.pdf [accessed: 5.02.2025]. Article 16 of the Code of Medical Ethics stipulates that a physician may conduct diagnostic, therapeutic, and preventive procedures only with the patient's informed consent, except in specific cases such as emergencies, legal mandates, or when consent must be obtained from an authorized representative due to the patient's incapacity.

10 Importantly, in cases where consent has not been obtained, the provision of medical services may result not only in civil liability for damages, but also in criminal liability. In particular, Article 192 of the Polish Penal Code stipulates that anyone who performs a medical procedure without the patient's consent is liable to a fine, restriction of liberty or imprisonment for up to two years. This provision underlines the fundamental nature of patient autonomy and the legal necessity of obtaining valid consent before any medical intervention.

- Consent must be given by the patient themselves or an authorised entity[11]. In cases where the patient is legally incapable of providing consent, it must be substituted by an authorised representative or a court decision.
- The consenting individual must be adequately informed, fulfilling the requirement of informed consent. This entails providing the patient with a clear and comprehensible explanation of the proposed medical intervention, including its nature, objectives, risks, and possible alternatives.
- Consent must be given voluntarily and be sufficiently specific. It must be provided without coercion or undue influence and should clearly define the scope of the medical procedures to be performed.
- The form of consent must comply with legal provisions, which prescribe specific modes of declaration for certain procedures or treatments, such as invasive interventions or experimental therapies[12].

In the context of medical artificial intelligence, particular attention must be paid to the requirement of informed consent. This obligation is closely linked to another patient right, namely the right to information.

Patient's right to information

The scope of information provided to the patient is explicitly regulated under Polish law, particularly in Article 31 of the Act on the

[11] See: Article 17 of the Patients' Rights Act. Under this provision, medical treatment of a patient under 16 years of age requires the consent of their statutory representative. For patients aged 16 or older but still under 18, both the patient and their statutory representative must consent jointly. In case of disagreement between the minor and the representative, the matter is resolved by the court.

[12] D. Karkowska, B. Kmieciak, *Art. 16*, [in:] *Prawa pacjenta i Rzecznik Praw Pacjenta. Komentarz*, red. E. Bielak-Jomaa, G. Błażewicz, R. Bryzek, B. Chmielowiec, M. Ćwikiel, P. Grzesiewski, A. Nowak, D. Karkowska, B. Kmieciak, Warszawa 2021, LEX/el.; P. Konieczniak, *Zgoda pacjenta – uwagi wprowadzające*, [in:] *Regulacja prawna czynności medycznych*, red. M. Boratyńska, P. Konieczniak, E. Zielińska, "System Prawa Medycznego", t. 2, cz. 1, Warszawa 2019, LEX/el.

Professions of Physician and Dentist and Article 9 of the Patients' Rights Act. In accordance with the prevailing legal provisions, the information that is to be provided to the patient must encompass the following components:

- The patient's health status and diagnosis;
- The proposed and possible diagnostic and therapeutic methods;
- The consequences of both implementing and refraining from the proposed and available diagnostic and therapeutic methods;
- The expected treatment outcomes and prognosis[13].

Furthermore, in accordance with Article 14(3) KEL, the information provided to the patient should be easily understandable. This aligns with Article 31(1) of the Act on the Professions of Physician and Dentist, which explicitly requires the physician to communicate information in an 'accessible' manner. An identical provision can be found in Article 9(2) of the Patients' Rights Act[14].

Under Polish law, there are broadly two situations in which a patient may not receive the full scope of information guaranteed by the legislation on the right to information. The first occurs when the patient specifically asks to limit the information provided by the physician. This means that a patient has the right to refuse certain medical details if they do not wish to receive them. Such a request legally exempts the physician from his obligation to disclose full information. This limitation is expressly recognised in Article 31(3)

[13] The specified scope of information has been explicitly indicated in the following legal provisions: Article 31(1) of the Act on the Professions of Physician and Dentist, and Article 9(2) of the Patients' Rights Act. P. Konieczniak, *Prawo do informacji zindywializowanej*, [in:] *Regulacja prawna czynności medycznych*, *op. cit.*; wyrok Sądu Najwyższego z dnia 6 grudnia 2023 r. [Supreme Court Judgment of December 6, 2023], II CSKP 804/22, LEX No. 3754910; wyrok Sądu Najwyższego z dnia 24 września 2020 r. [Supreme Court Judgment of September 24, 2020], IV CSK 49/19, LEX No. 3057399.

[14] Wyrok Wojewódzkiego Sądu Administracyjnego w Warszawie z dnia 8 sierpnia 2019 r. [Judgment of the Administrative Court in Warsaw of August 8, 2019], VII SA/Wa 386/19, LEX No. 3079478; Judgment of the Supreme Court of September 24, 2020, IV CSK 49/19.

of the Act on the Professions of Physician and Dentist, in Article 9 (4) of the Patients' Rights Act and in Article 17 (1) KEL[15].

The second situation occurs when the decision to withhold certain information is made by the physician, and is referred to as therapeutic privilege[16]. However, its utilisation is permissible only in exceptional circumstances and is subject to legal restrictions. Specifically, the physician may limit the information provided to the patient only if the following conditions are met simultaneously: the patient's prognosis is unfavorable, indicating a serious or terminal condition; there exists an extraordinary situation justifying the withholding of information, and the decision to restrict information is in the best interest of the patient, meaning that full disclosure could potentially cause harm, such as severe psychological distress or a decline in the patient's condition[17]. Taken together, these conditions act as guarantees to ensure that any restriction on patient information remains a rare and carefully justified exception, rather than a routine practice. The legal basis for therapeutic privilege is set out in Article 31(4) of the Act on the Professions of Physician and Dentist, in Article 9(6) of the Patients' Rights Act and in Article 18 KEL.

Although the right to information is a fundamental principle of patient autonomy, the legal provisions referred to above acknowledge that, in specific cases, a more nuanced approach may be required to balance ethical, medical, and psychological considerations.

Artificial intelligence in healthcare

In the context of medical AI, ensuring a patient's right to provide informed consent, including meeting all requirements related to

[15] P. Konieczniak, *Możliwość zrzeczenia się informacji*, [in:] *Regulacja prawna czynności medycznych*, *op. cit*.

[16] M. Boratyńska, *Gwarancje dla pacjenta*, [in:] *Regulacja prawna czynności medycznych*, *op. cit*.

[17] This follows, among others, from: Article 31(4) of the Act on the Professions of Physician and Dentist. P. Konieczniak, *Kompetencja do wyłączenia przywileju terapeutycznego*, [in:] *Regulacja prawna czynności medycznych*, *op. cit*.

the scope of information, may raise concerns and challenges. AI technologies introduce complexity into the patient-physician relationship, particularly in terms of transparency in decision-making processes[18]. However, prior to addressing these concerns, it is worthwhile to consider the application of AI in the healthcare sector. Understanding the scope of AI applications allows for a more precise assessment of the legal and ethical implications associated with patient consent and the disclosure of AI involvement in clinical decision-making.

There are numerous potential applications of artificial intelligence in healthcare, which can be broadly categorized into two main areas: administrative and clinical. The first category includes AI solutions that can be implemented both at the level of individual healthcare providers and across healthcare systems. In this context, AI can influence resource allocation in healthcare systems, public health management and healthcare processes[19]. This category also includes AI-enabled solutions that are only indirectly involved in patient care, but aim to streamline the delivery of healthcare services. Examples of such applications include remote appointment scheduling and management platforms, chatbots, and electronic document management software (e.g. NEWTON Dictate, which provides speech recognition and transcription, including medical terminology)[20]. Essentially, these solutions are not significantly different from similar technologies used outside of healthcare. The second category comprises AI applications directly involved in the provision of healthcare services, encompassing all clinical applications. These

[18] A. Sauerbrei, A. Kerasidou, F. Lucivero, N. Hallowell, *The impact of artificial intelligence on the person-centred, doctor-patient relationship: some problems and solutions*, "BMC Medical Informatics and Decision Making" 2023, vol. 23, no. 1, article 73, pp. 1–15.

[19] S.M. Varnosfaderani, M. Forouzanfar, *The role of AI in hospitals and clinics: Transforming healthcare in the 21st century*, "Bioengineering (Basel)" 2024, vol. 11, no. 4, art. 337; M. Ramezani, A. Takian, A. Bakhtiari, H.R. Rabiee, A.A. Fazaeli, S. Sazgarnejad, *The application of artificial intelligence in health financing: A scoping review*, "Cost Effectiveness and Resource Allocation" 2023, vol. 21, art. 83.

[20] *NEWTON Dictate Professional solution for converting human voice into text*, newtontech.net/en/newton-dictate [accessed: 28.02.2025].

solutions aim to enhance patient care, diagnostics, and treatment processes. While this category is highly diverse, it can be broadly classified into two main groups: assistive and advisory.

Assistive AI and informed consent

Assistive AI consists of technologies that merely facilitate or supplement the provision of healthcare services. For instance, in radiology, AI algorithms can enhance image quality, detect specific pathologies in medical images (e.g., OsteoDetect identifies bone fractures[21]), and, in more advanced applications, recognize multiple types of pathologies (e.g., Icobrain identifies neurological changes associated with multiple sclerosis, epilepsy, and dementia[22]). In oncology, for example, AI is employed to analyze mammographic images for the early detection of breast cancer; a notable example of such a tool is Mia (Mammography Intelligent Assessment)[23].

AI-enabled technologies in this category serve only as an adjunct to healthcare services and remain fully supervised and controlled by qualified medical professionals. As long as AI and other emerging technologies maintain a purely supportive role in the healthcare process – operating under the full supervision of appropriately qualified healthcare providers – there is no need for additional regulatory frameworks in this domain. In this context, AI-based solutions function merely as advanced diagnostic tools rather than autonomous decision-makers – analogous to replacing an older X-ray machine with a more advanced model. These technologies build upon established medical practices, improving efficiency and

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21 Imagen, *Diagnostyka obrazowa najwyższej jakości jako usługa*, imagen.ai [accessed: 28.02.2025].

22 *Icometrix – Enabling value-based care for people with neurological conditions*, icometrix.com [accessed: 28.02.2025].

23 Mia is currently being evaluated in the UK's largest AI-based breast cancer screening trial, which aims to optimise screening performance and improve patient outcomes (the trial is targeting 700,000 mammograms). *World-leading AI trial to tackle breast cancer launched*, 4.02.2025, gov.uk/government/news/world-leading-ai-trial-to-tackle-breast-cancer-launched [accessed: 28.02.2025].

precision while ensuring adherence to existing clinical protocols. Their integration does not alter the fundamental structure of medical decision-making but rather augments the capabilities of healthcare professionals in delivering high-quality care. Consequently, AI applications in this category should be regarded as an evolutionary enhancement of medical tools rather than a disruptive force within traditional healthcare frameworks.

AI can thus be considered a well-integrated method within clinical practice that does not necessitate additional patient consent or disclosure requirements[24].

Advisory AI and informed consent

The second group comprises AI technologies that, in addition to facilitating healthcare delivery, actively contribute to decision-making processes related to medical services. For instance, an AI algorithm may analyze symptoms and patient data to recommend an appropriate therapy, surgical approach, or pharmacological treatment.

The existing legal framework presents numerous challenges in interpretation concerning the use of advisory AI technologies. These challenges are particularly relevant to the application of laws governing patient rights, such as the right to information and informed consent[25].

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[24] I.G. Cohen, A. Slottje, *Artificial intelligence and the law of informed consent*, [in:] *Research handbook on health, AI and the law*, eds B. Solaiman, I.G. Cohen, Cheltenham 2024, p. 173.

[25] M. Gerardi, K. Barud, M.-C. Wagner, N. Forgo, F. Fallucchi, N. Scarpato, F. Guadagni, F.M. Zanzotto, *Active informed consent to boost the application of machine learning in medicine*, arXiv preprint arXiv:2210.08987, 2022; C.T. Okolo, A.M. González, *IAC: A framework for enabling patient agency in the use of AI-enabled healthcare*, arXiv preprint arXiv:2111.04456, 2021; S. Gerke, T. Minssen, I.G. Cohen, *Ethical and legal challenges of artificial intelligence-driven healthcare*, [in:] *Artificial intelligence in healthcare*, eds A. Bohr, K. Memarzadeh, Amsterdam 2020, pp. 295–336; J. Morley, C.C.V. Machado, C. Burr, J. Cowls, I. Joshi, M. Taddeo, L. Floridi, *The ethics of AI in health care: A mapping review*, "Social Science & Medicine" 2020, vol. 260, 113172; European Parliament, *Artificial intelligence in healthcare: Applications, risks,*

To illustrate the intersection of advisory AI and informed consent, consider a scenario in which a patient is diagnosed with cancer and faces two primary treatment options: active surveillance or surgical intervention. The physician utilizes an AI system capable of recommending a treatment plan based on factors such as the patient's age, tumor size, and medical history of similar cases. This scenario gives rise to several critical questions: What specific information should be disclosed to the patient regarding the use of AI in their treatment planning? Should the patient be explicitly informed that AI contributes to the evaluation of their medical options? Furthermore, is it necessary for the patient to know whether the physician's decision aligns with or diverges from the AI's recommendation? Additionally, an important legal consideration arises: Does the principle of informed consent necessitate that AI-enabled technologies provide justifications for their recommendations so that these justifications can be communicated to the patient?

The existing legal doctrine of informed consent does not currently mandate the disclosure of AI use in medical decision-making. However, the fundamental question is whether patients should be informed of the role of AI in their individual cases. This issue remains subject to debate. On the one hand, it has been posited that: "hospitals and health-care providers are unlikely to inform patients that AI was used as a part of decision-making to guide, validate or overrule a provider. There is, however, no precedent for seeking the consent of patients to use technologies for diagnosis or treatment"[26].

In accordance with Polish legislation and the aforementioned scope of information disclosure, this obligation pertains to "the proposed and possible diagnostic and therapeutic methods", and not the tools that facilitate their implementation. In a traditional medical context, these tools typically comprise a physician's knowledge and experience. In clinical decision support, AI recommendations

and ethical and societal impacts, Brussels 2022; World Health Organization, *Ethics and governance of artificial intelligence for health: WHO guidance*, Geneva, 2021, iris.who.int/bitstream/handle/10665/341996/9789240029200-eng.pdf [accessed: 17.02.2025].

[26] World Health Organization, *Ethics and governance of artificial intelligence*…, *op. cit.*, p. 47.

may be viewed as just another source of information, analogous to medical training or experience. Since physicians are not required to disclose every informational source underlying their decisions, they may similarly not be obligated to specify AI's role.

Furthermore, it is imperative that medical professionals have access to AI-enabled technologies if such technologies are to become integral to the prevailing standard of care. This necessity arises from the fact that these technologies will increasingly embody current medical knowledge. Under Polish legislation on patient rights, which aligns with analogous laws in other jurisdictions, patients have the right to "health services conforming to the requirements of current medical knowledge"[27]. Similarly, Article 6(1) of the Code of Medical Ethics stipulates that a physician must not employ methods that are scientifically unverified or recognized by the scientific community as harmful or devoid of value. In the Polish legal system, the term 'current medical knowledge' is not statutorily defined. However, the concept has been systematically examined in judicial rulings and legal doctrine[28]. According to case law, current medical knowledge encompasses

> the entirety of medical knowledge, including theses substantiated by documented and systematically formalised clinical research. Methods considered valid and approved for use are those based on principles of knowledge endorsed by reputable scientific bodies. These principles must align with widely accepted views within the scientific community, which are generally undisputed and supported by near-unanimous consensus[29].

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[27] Article 6(1) of the Patients' Rights Act.

[28] M. Serwach, *Niezgodność z aktualną wiedzą medyczną*, [in:] *Odpowiedzialność prawna w związku z czynnościami medycznymi*, red. T. Dukiet-Nagórska, A. Liszewska, E. Zielińska, "System Prawa Medycznego", t. 3, Warszawa 2021; M. Kopeć, [in:] *Ustawa o zawodach lekarza i lekarza dentysty. Komentarz*, red. M. Kopeć, Warszawa 2016, p. 42; J. Haberko, *Aktualna wiedza medyczna a stosowanie homeopatii*, "Medyczna Wokanda" 2009, nr 1, s. 50–51.

[29] Wyrok Wojewódzkiego Sądu Administracyjnego w Warszawie z dnia 12 czerwca 2019 r. [Judgment of the Administrative Court in Warsaw of June 12, 2019], VI SA/Wa 557/19, LEX No. 2720242.

If AI-based solutions satisfy the criteria for current medical knowledge, their integration into clinical practice should be considered – regardless of whether their use is explicitly disclosed to patients.

On the other hand, the literature, including guidelines proposed by the WHO, emphasizes that "the use of AI in medicine and failure to disclose its use could challenge the core of informed consent and wider public trust in health care"[30]. This argument is particularly compelling when AI systems are used not merely to automate routine tasks but also to interpret data and influence clinical decision-making. If an AI-generated recommendation results in a different treatment choice than a physician might have independently selected and relies on patterns that are undetectable to human judgment, the system may effectively function as the primary decision-maker. In such cases, it is argued that patients should be engaged in the decision-making process and be granted the right to information[31].

Assuming the necessity of informed patient consent for the utilisation of advisory AI, it is imperative to ascertain the precise details that should be disclosed to patients, ensuring the validity of their consent within the context of AI-based technology. In this context, the well-known 'black-box' problem emerges[32]. AI-based systems rely on complex algorithms and probabilistic models, which may be difficult for patients to comprehend. The intricacy and lack of transparency of artificial intelligence solutions can compromise the relationship between patients and healthcare providers by undermining both transparency and mutual trust. This is a crucial aspect of care that must be prioritised to ensure effective treatment and maintain trust between patients and healthcare providers. Patients may feel a loss of control and autonomy, particularly when medical

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30 World Health Organization, *Ethics and governance of artificial intelligence*…, *op. cit*., p. 47.

31 I.G. Cohen, A. Slottje, *Artificial intelligence and the law of informed consent*, *op. cit*., p. 173.

32 A. Kiseleva, D. Kotzinos, P. De Hert, *Transparency of AI in healthcare as a multilayered system of accountabilities: Between legal requirements and technical limitations*, "Frontiers in Artificial Intelligence" 2022, vol. 5, p. 879603.

decisions are opaque and when shared decision-making between patients and physicians is absent[33].

Therefore, ensuring that information is presented in an accessible and comprehensible manner is crucial to fulfilling the legal requirements of informed consent. Physicians must take particular care to explain how AI-generated recommendations are formulated, their potential limitations, and any inherent uncertainties associated with their use. However, it is essential to assess whether such expectations are feasible. To address this question, one must first examine whether doctors themselves will be able to understand how the AI-based technology they use operates.

The complexity of AI systems poses significant challenges in terms of full disclosure and comprehension, as both physicians and patients may struggle with the requisite understanding of machine learning. Furthermore, the more effective an AI system is, the more difficult it tends to be to explain. However, it should be noted that informed consent does not necessitate absolute transparency. Just as patients are not expected to have a comprehensive understanding of pharmacology, they likewise may not be required to comprehend the intricacies of AI's reasoning processes, as long as they are able to make autonomous decisions[34].

It is proposed that a potential solution could be that a physician may not need to understand the underlying mechanisms of an AI system, only that it produces reliable outcomes. If its accuracy is supported by clinical trials, approval of regulatory authorities, or personal experience, AI can be trusted like any other empirical medical knowledge, even without full transparency regarding its reasoning[35]. It has been suggested that an analogy can be drawn between the utilisation of AI recommendations and the reliance of a junior doctor on the counsel of a senior professional, or of a generalist on the expertise of a specialist. This underscores the concept

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33 C. Mennella, U. Maniscalco, G. De Pietro, M. Esposito, *Ethical and regulatory challenges of AI technologies in healthcare: A narrative review*, "Heliyon" 2024, vol. 10, no. 4, e26297.

34 I.G. Cohen, A. Slottje, *Artificial intelligence and the law of informed consent*, *op. cit*., p. 178.

35 *Ibidem*, p. 176.

that placing trust in expert counsel can be beneficial to the patient, even in situations where the entirety of the information is not fully comprehended[36]. It is acknowledged that, in principle, the information provided has the capacity to be very general in nature, with a focus on the overall functioning of AI systems as opposed to technical details[37].

An alternative approach to addressing the challenge of AI information disclosure is to define key areas that physicians should understand when using AI. These areas include: (1) how AI systems function; (2) their transparency and trustworthiness; (3) their limitations and possible errors; (4) methods for resolving disagreements between physicians and AI; (5) the security of patient data and AI systems; (6) the reliability and validation of AI systems; and (7) the presence of potential bias in AI programs[38].

Another approach suggests applying therapeutic privilege in the context of AI use in healthcare as a means of limiting information disclosure[39]. This approach concerns the scope of informed consent and whether withholding details about AI involvement could be justified. However, this approach risks veering into a form of medical paternalism, which assumes that patients are incapable of comprehending the intricacies of AI, its clinical efficacy, and consequently, their own capacity to make effective decisions regarding their treatment[40]. Nonetheless, justifying therapeutic privilege in this case is difficult, as AI's use does not inherently pose risks that would warrant nondisclosure. Instead, transparency about AI-assisted decisions is essential for maintaining patient trust and ensuring informed decision-making. Therefore, invoking

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36 I.G. Cohen, *Informed consent and medical artificial intelligence: What to tell the patient?*, "Georgetown Law Journal", vol. 108, no. 5, p. 1459.

37 M. Pruski, *AI-enhanced healthcare: Not a new paradigm for informed consent*, "Journal of Bioethical Inquiry" 2024 vol. 21, no. 3, p. 479.

38 K.V. Iserson, *Informed consent for artificial intelligence in emergency medicine: A practical guide*, "The American Journal of Emergency Medicine" 2024, vol. 76, no. 2, pp. 225–230.

39 P. Nolan, *Artificial intelligence in medicine – is too much transparency a good thing?*, "Medico-Legal Journal" 2023, vol. 91, no. 4, pp. 193–197.

40 I.G. Cohen, A. Slottje, *Artificial intelligence and the law of informed consent*, *op. cit*., p. 179.

therapeutic privilege in this context should remain an exception rather than a normative practice.

An alternative perspective holds that patients should be informed upfront about AI's role if it substantially influences the diagnostic or therapeutic process. This approach, akin to therapeutic privilege, incorporates an element of discretion, as it is the physician who assesses whether the AI solution employed exerts a significant influence on the diagnostic or therapeutic process. As with therapeutic privilege, this model raises concerns about potential misuse by physicians and the erosion of trust within the doctor–patient relationship[41].

Although no specific legal regulations have yet been established regarding the disclosure of AI involvement in medical decision-making, it may ultimately prove unnecessary to introduce such regulations. In this view, AI can be considered a well-integrated component of clinical practice that does not necessitate additional patient consent or disclosure requirements. If AI-based recommendations are treated as an extension of medical expertise rather than a separate decision-making entity, existing legal frameworks on informed consent could be sufficient[42]. However, the integration of AI in healthcare gives rise to a significant ethical and legal issue: should there be a legally recognized right for patients to decline AI-assisted medical services[43]?

Right to refuse AI-based treatment

If a patient is informed about the use of AI in their diagnosis or treatment and subsequently refuses to consent to its application, several critical questions emerge: should healthcare providers respect this refusal and offer an alternative, human-driven approach, even

41 R. Kubiak, *Przywilej terapeutyczny*, "Medycyna Paliatywna" 2017, vol. 9, no. 1, pp. 12–20.

42 M. Pruski, *AI-Enhanced Healthcare…*, *op. cit.*

43 B.I. de Miguel, *Should we have a right to refuse diagnostics and treatment planning by artificial intelligence?*, "Med Health Care Philos" 2020, vol. 23, no. 2, pp. 247–252; T. Ploug, S. Holm, *The right to refuse diagnostics and treatment planning by artificial intelligence*, "Med Health Care Philos" 2020, vol. 23, no. 1, pp. 107–114.

if it is potentially less accurate or efficient? Would denying AI-assisted care compromise the standard of treatment? Additionally, how should healthcare institutions navigate the balance between respecting patient autonomy and ensuring optimal clinical outcomes? The aforementioned points merely address a select number of the most pressing issues that arise in the context of the possible right of patients to refuse healthcare services that utilise AI.

Currently, there is no explicit legal right for patients to refuse automated medical decision-making, nor does the EU AI Act establish such a right. However, Article 22 of the General Data Protection Regulation (GDPR)[44] provides individuals with the right not to be subject to decisions based solely on automated processing. It is proposed that a 'health-conformant' interpretation of Article 22 GDPR be applied to medical decision-making, enhancing patient protection by reinforcing transparency, ensuring human oversight, and enabling contestation of AI-driven decisions[45].

Notwithstanding the recognition of patients' right to refuse AI-driven treatment, the consistent availability of a non-AI alternative remains uncertain[46]. In cases where a patient refuses AI-assisted treatment while still requiring medical care, such a decision may be likened to rejecting contemporary medical interventions in favor of outdated practices, such as bloodletting[47]. Moreover, healthcare professionals may be reluctant to offer non-AI-based care if it deviates from established professional standards and legal obligations[48].

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[44] Regulation (EU) 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, GDPR).

[45] H.B. van Kolfschooten, *A health-conformant reading of the GDPR's right not to be subject to automated decision-making*, "Medical Law Review" 2024, vol. 32, issue 3, pp. 373–391; this is in light of the recent ruling by the Court of Justice of the European Union (CJEU) in the SCHUFA case (C-634/21), which addressed the matter of automated credit scoring.

[46] M. Pruski, *AI-Enhanced Healthcare…*, *op. cit.*, p. 484; despite the WHO guidance to the contrary.

[47] *Ibidem*.

[48] C. Mennella, U. Maniscalco, G. De Pietro, M. Esposito, *Ethical and regulatory challenges of AI technologies in healthcare…*, *op. cit.*

As AI integration advances, providing non-AI care may become inefficient and unsustainable. While ethical considerations support a patient's right to refuse AI, practical and cost-effectiveness concerns may limit the availability of non-AI alternatives in certain cases. Pruski's hypothesis, that in future, guaranteeing patient access to non-AI-enhanced healthcare may be impossible, is not easily refutable. The present situation is analogous to the lack of manual alternatives to automated healthcare processes that are currently offered[49].

A proposed solution to safeguarding patients from potential risks associated with the integration of AI in healthcare is not to impose an excessively complex or burdensome informed consent process. Instead, emphasis should be placed on the thorough evaluation and robust regulation of AI technologies[50]. By ensuring that AI systems meet stringent safety, accuracy, and ethical standards before their implementation in clinical practice, regulatory frameworks can provide a more effective means of protecting patient welfare. This approach shifts the focus from placing the burden of decision-making solely on patients to establishing systemic safeguards that uphold the quality and reliability of AI-driven healthcare[51].

Concluding remarks

The legal frameworks governing informed consent do not explicitly mandate the disclosure of AI involvement; however, ethical considerations underscore the importance of transparency in maintaining patient trust. Informed consent remains a cornerstone of medical ethics and law, ensuring that patients receive comprehensive information to make autonomous decisions about their healthcare. Physicians play a crucial role in this process, bearing the responsibility of adequately informing patients, understanding their preferences, and engaging them in shared decision-making. These considerations highlight the necessity of establishing clear guidelines on patient consent in AI-integrated healthcare. The question of whether

49 M. Pruski, *AI-Enhanced Healthcare…*, *op. cit.*

50 *Ibidem*, p. 485.

51 *Ibidem*.

individuals should have the right to opt out of AI-assisted medical decision-making poses a challenge to traditional notions of patient autonomy while reflecting the evolving role of AI in clinical practice. If AI becomes the standard for medical decision-making, explicit disclosure requirements may no longer be legislatively mandated. However, healthcare providers should remain transparent when patients inquire about AI involvement, and refusals of AI-assisted care should be respected. Nevertheless, rejecting AI-driven healthcare in the future may become impractical. Given these complexities, regulatory efforts should prioritize the development of AI systems that meet rigorous ethical, safety, and transparency standards.

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Abstract
Medical artificial intelligence and informed consent

There is no legal consensus on how to ensure the protection of patients' rights in the face of medical artificial intelligence (AI). This paper examines the legal frameworks governing informed consent, including international conventions and Polish legislation, and their applicability to AI-assisted medical decisions. The discussion highlights challenges in ensuring transparency, patient understanding, and the ethical implications of AI's role in clinical decision-making. The paper further explores whether patients should be informed of AI involvement in their treatment and whether they should have the right to refuse AI-based medical services. The findings suggest that while AI can enhance healthcare delivery, maintaining trust and respecting patient autonomy require clear legal and ethical guidelines regarding AI's role in medical decision-making.
Key words: medical artificial intelligence, informed consent, patient rights, healthcare law, medical ethics, AI in healthcare, legal frameworks, patient autonomy