

Informed Consent for the Use of AI in the Process of Providing Medical Services

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Abstract: It has been for several years now that physicians use medical devices based on artificial intelligence (AI) in their professional practice. The use of these tools makes health services more personalized, tailored to the individual characteristics and needs of the patient. There is also a technological possibility for AI systems to provide patients with information regarding their health condition and treatment methods. The use of medical devices equipped with AI creates new types of risk, including the risk of algorithmic error, the risk of cyber-attack, and the risk of algorithmic mismatch (false-positive or false-negative results). Most patients do not know these tools, so not everyone will trust them. Obtaining informed consent from the patient is a necessary condition for any medical intervention. This study attempts to answer the following questions: (1) Is there a legal possibility to provide AI with the ability to inform the patient about their health condition and proposed treatment methods?; (2) Does the unpredictability and opacity of AI behavior affect the scope of information that should be provided to the patient before medical intervention?; (3) What information should the physician provide to the patient for this consent to be considered informed?; (4) Should the patient always be informed that AI was involved in the diagnosis or therapeutic process? The presented study uses comparative law methodology. American, Belgian and German law are analyzed.

1. Introduction

It has been for several years now that physicians use medical devices based on artificial intelligence (AI) in their professional practice. These tools make health services more personalized, tailored to the individual characteristics and needs of the patient. AI devices make it possible to gain insight into and then use biological relationships that would be impossible to discover otherwise.¹ The use of artificial intelligence creates new types of risk, including the risk of algorithmic error, the risk of cyber-attack, and the risk of algorithmic mismatch (false-positive or false-negative results). There is also a technological possibility for AI systems to provide patients with information regarding their health condition and treatment methods. Patients are not familiar with these tools, so not everyone will trust them. Medical intervention requires obtaining informed consent from the patient. This study will consider whether and to what extent consent to a medical intervention using AI should differ from the consent given to a medical intervention using traditional methods and analyze the legal possibility of AI providing information on the patient's health condition and proposed treatment methods.

2. Informed Consent

Obtaining patient consent is a *sine qua non* condition for the legality of any medical interventions.² According to Article 32(1) of the Act on the Professions of Physician and Dentist,³ except for situations specified in the law, a physician may conduct an examination or provide other health services only after obtaining the patient's consent. Obtaining such consent legitimizes medical intervention taken by the healthcare provider, eliminating the unlawfulness of their actions, which would involve interference with personal rights in the form of bodily integrity. Consent shifts the risk of side effects and other undesirable treatment outcomes from the

¹ Price Nicholson II, "Describing Black-Box Medicine," *Boston University Journal of Science and Technology Law* 21, no. 2 (Summer 2015): 347–8.

² Rafał Kubiak, *Prawo medyczne* (Warsaw: C.H. Beck, 2010), 339.

³ Act on the Professions of Physician and Dentist of 5 December 1996, *Journal of Laws* 1997, No. 28, item 152.

physician to the patient. Case law has established⁴ that a patient who consents to a surgical procedure takes the risk associated with the procedure, including its direct, typical, and ordinary consequences, about which they should be properly informed.

This raises the question of whether a patient can be held responsible for the risks associated with the unpredictability of artificial intelligence's actions as a result of giving consent. If so, to what extent and what information should the physician provide to the patient for the consent to be considered conscious, aware, and informed?⁵ Should the patient always be informed that artificial intelligence is/will be involved in the diagnostic process or surgical procedure? How detailed should this information be? Should the patient be informed why the artificial intelligence made a specific diagnosis? What should the physician tell the patient about the artificial intelligence system?

An attempt to answer these questions should begin with a reminder that according to Article 9(2) of the Patient Rights and Patient Ombudsman Act,⁶ the legislator obliges physicians to provide patients with comprehensive information about their health condition, diagnosis, proposed and possible diagnostic and treatment methods, foreseeable consequences of their application or omission, treatment results, and prognosis, within the scope of healthcare services provided by that physician. In the case of surgical procedures, patients are informed, among other things, about the method of performing the procedure and its risks.⁷ Furthermore, according to Article 13(3) of the Medical Ethics Code, a physician is obliged to inform the patient not only about the planned diagnostic and therapeutic methods but also about all available ones, as well as about the risks associated with the use of any of them. Detailed explanation is required for the method

⁴ Polish Supreme Court, Judgment of 28 August 1972, Ref. No. II CR 196/72, OSN 1973, No. 5, item. 86.

⁵ Małgorzata Świdarska, *Zgoda Pacjenta na zabieg medyczny* (Toruń: Dom Organizatora, 2007), 17.

⁶ Act on the Patient Rights and Patient Ombudsman of 6 November 2008, Journal of Laws 2009, No. 52, item 417, as amended.

⁷ Rafał Patryn and Sylwia Kielbasa, "Zasady prawno-formalnego postępowania lekarza w kontekście świadomej zgody pacjenta i obowiązku zachowania tajemnicy lekarskiej," *Internetowy Przegląd Prawniczy TBSP UJ*, no. 4 (2015): 86, accessed April 24, 2023, <https://ruj.uj.edu.pl/server/api/core/bitstreams/9dcdbb53-72ca-48a6-9c91-c9044da91a86/content>.

proposed by the physician, which they consider to be the most beneficial for the patient, as well as any complications resulting from the use of this method. From the above-mentioned provisions, it follows that, as a rule, a physician is obligated to inform the patient or their legal representative about the consequences and risks of a medical procedure in every case.⁸

3. Automatization of Providing Information and Consent

It is technologically possible to automate the provision of information about the patient's health condition and proposed treatment methods. It should be emphasized that information about the diagnosis differs from information on suggested treatment methods. In terms of the effective use of human resources, this solution seems beneficial. On the other hand, medical literature indicates that the relationship between physician and patient is one of the most important elements of an effective therapeutic process. In legal literature it is recognized that this relationship is characterized by trust⁹ resulting from the patient's belief that the physician will treat them with due attention in every situation, not as the subject of medical procedures, but as a partner in the treatment process, sharing with them information about their health condition and responsibility for the final effect of treatment.¹⁰ The quality of contact between the doctor and the treated person, the method of providing important information, the appropriate choice of words, the amount of time devoted to the patient, as well as the entire non-verbal side of the message addressed to the patient are important in the recovery process.¹¹ When providing information, physicians should take into account the patient's ability to understand the information they provide. This depends on patient's intellectual capabilities and their emotional state, but also on other circumstances surrounding the provision of information.¹² Artificial intelligence, unlike

⁸ Anna Stychlerz, "Zakres informacji przekazywanych pacjentowi," *Forum Medycyny Rodzinnej* 2, no. 6 (November 2018): 471–3.

⁹ Świdarska, *Zgoda Pacjenta*, 99.

¹⁰ Justyna Szpara, "Prawo do informacji medycznej w relacjach pacjenta z lekarzem," *Prawo i Medycyna* 1, no. 4 (Winter 1999): 135.

¹¹ Ewa Ogłodek, Danuta Moś, and Aleksander Araszkiwicz, "Zasady kontaktu terapeutycznego lekarza z pacjentem," *Zdrowie Publiczne* 119, no. 3 (Winter 2009): 331.

¹² Brian Pickering, "Trust, but Verify: Informed Consent, AI Technologies, and Public Health Emergencies," *Future Internet* 14, no. 5 (May 2021): 20; Jan Ciechorski, "Głosa do wyroku Sądu Apelacyjnego w Gdańsku z dnia 28 listopada 2012, V ACA 826/12," *Palestra*, no. 1–2

a physician, cannot take into account circumstances related to the patient's emotions.

The World Health Organization has published guidance on Ethics and governance of artificial intelligence for health. The WHO has introduced six ethical principles for the design and use of AI. The first one is the protection of human autonomy. According to this principle, humans should maintain full control over AI and the health care system, and make medical decisions independently.¹³ The EU legislator also emphasizes respect for human autonomy and the need to supervise AI. According to Article 4a of the draft of Artificial Intelligence Act, AI should be developed and used as tools that serve people, respect human dignity and personal autonomy and operate in a way that humans can appropriately control and supervise.¹⁴ The principle of human autonomy was also indicated in the draft convention on artificial intelligence, human rights, democracy and the rule of law developed by the Council of Europe Committee on Artificial Intelligence.¹⁵

Giving an AI system (e.g. a virtual assistant) the competence to provide information on health and obtain consent for diagnostic and therapeutic activities would be contrary to the Act on the Professions of Physician and Dentist, i.e. articles 31–34. According to these regulations, only a physician can obtain consent from the patient and provide them with health services, except for nursing and midwifery services. Therefore, only by obtaining effective consent from the patient, after adequately informing them about the risks associated with the use of artificial intelligence (e.g. a surgical robot) and the proposed alternative treatment methods using the AI system,

(January/February 2014): 159; Marcin Kopeć, “Art. 31,” in *Ustawa o zawodach lekarza i lekarza dentysty. Komentarz*, eds. Elżbieta Buczek et al. (Warsaw: Wolters Kluwer 2016), Lex/el.

¹³ World Health Organization, “Ethics and governance of artificial intelligence for health: WHO guidance,” Geneva 2021, 25, accessed May 17, 2023, <https://www.who.int/publications/i/item/9789240029200>.

¹⁴ Amendments adopted by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021)0206 – C9–0146/2021 – 2021/0106(COD)).

¹⁵ Draft Framework Convention on artificial intelligence, human rights, democracy and the rule of law, Committee on Artificial Intelligence (CAI), pp. 3–5, accessed May 15, 2024, <https://rm.coe.int/-1493-10-1b-committee-on-artificial-intelligence-cai-b-draft-framework/1680aee411>.

and subsequent performance of the procedure under the rules of medical practice, can the doctor be released from liability for interference with the patient's bodily integrity.

The use of artificial intelligence systems, chatbots and other tools to provide information and obtain consent for a procedure would require an amendment to the Act on the Professions of Physician and Dentist. In my opinion, this is unacceptable due to the key role of the relationship between physician and patient. In most cases, there are several diagnostic and therapeutic methods. Artificial intelligence can be programmed to select specific treatment methods most beneficial to the software manufacturer or healthcare provider, and not necessarily to the patient. Moreover, more invasive methods may bring much better results. It appears that it will be much more difficult for the patient to consent to such a method when the option is presented by an IT system or a non-human. A physician who is in an interpersonal relationship with the patient, builds trust, and has authority, will be able to convince the patient to use such a method. Moreover, the doctrine indicates that the patient is usually a layperson and has no knowledge about the intricacy and complexity of the diagnostic and therapeutic process, hence it should be assumed that the physician should do everything to convince the patient to choose the medical method that is optimal in the physician's opinion.¹⁶ They should be particularly careful when informing about the usefulness of various therapeutic methods when the patient prefers a method that is not very effective but is, for example, less invasive. Małgorzata Świdarska points out that if a particular medical procedure is needed and the patient neglects the recommendations or refuses to undergo such a procedure, the physician is obliged to make repeated attempts to convince them to undergo this procedure if they are in direct contact with them.¹⁷ Therefore, that obligation cannot be fulfilled by an artificial intelligence system. It can be argued that the physician, if they deem it helpful, can use an artificial intelligence system to convince the patient to use an effective treatment method and provide the patient with more comprehensive or better understandable information. However, they cannot stop there. In the author's opinion, they should do this only when

¹⁶ Świdarska, *Zgoda Pacjenta*, 131.

¹⁷ *Ibid.*

traditional methods of providing information are insufficient, or at the express request of the patient.

4. Informing the Patient about the Use of AI in the Treatment Process

The analysis of the obligation to inform patients about the use of artificial intelligence systems shall take American doctrine as the starting point. Informed consent as a legal concept has its source in American jurisprudence and doctrine, from where, with minor modifications, it was adopted into Canadian jurisprudence, and later also into German, French, Swiss and English law.¹⁸ American researchers were the first to analyze the obligation to inform patients about the use of AI in the treatment process. It is therefore probable that the doctrine, case law and legislation of other countries will also follow the solutions proposed by American researchers in matters of informed consent.

Gerald Cohen points out that in most cases, failure to inform the patient about the use of medical artificial intelligence will not constitute a violation of the right to give informed consent.¹⁹ He points out that when considering whether a physician should inform a patient about the use of artificial intelligence, reference should be made to the reasonable medical practitioner standard, according to which the physician should provide information that a reasonable physician would provide in the same or similar circumstances. According to the author, the effects of artificial intelligence can be considered as an element of the physician's thought process. If one could lay open the thought process of a typical physician deciding which surgical technique to use or whether to recommend a particular patient to undergo a particular type of treatment, one would find a lot of potential inputs. A physician can rely on vague memories from college lectures, what other doctors during their residency did in such cases, the latest research in leading medical journals, the experiences with and outcomes of the last 30 patients the physician saw, etc. There is no doubt that a physician who fails to describe each of these steps of the reasoning does not violate the

¹⁸ Ibid., 17–8.

¹⁹ I. Glenn Cohen, “Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?,” *The Georgetown Law Journal* 108 (May 2020): 1442.

law on informed consent.²⁰ Therefore, the consent of a person who has not read this data may be considered informed if other requirements are met. Gerald Cohen also points out that one can rely on the reasonable patient standard. The author compares AI with pharmaceuticals approved by the Food and Drug Administration (FDA).²¹ He believes that if doctors trust artificial intelligence as they trust FDA-approved drugs, and patients trust the doctor, then information about the use of an artificial intelligence system will not be required to obtain the patient's informed consent. It is necessary to create similar procedures for the approval of AI systems and to develop adequate indicators based on which the correctness of AI work could be checked.²²

On the other hand, the use of an autonomous self-learning tool may cause anxiety in the patient, for example, because these are new technologies, previously unknown in medicine. The patient has greater or lesser confidence in the correctness of the doctor's thought process and awareness of the elements that make up this process. However, they do not have to trust an abstract entity such as an IT system, which they cannot see, imagine how it works, or compare it with other experiences. When traditional treatment methods are used, the patient usually believes that a physician who has graduated studies and specialization, based on research from medical journals and their own experience, makes a correct diagnosis and properly conducts the patient's therapy. This belief comes from experience because most people participated or accompanied others in at least several therapeutic and diagnostic processes. Almost every patient took medication at some time in their life. However, most patients do not have experience with artificial intelligence systems. Therefore, they should not be expected to trust AI in this area, especially when legal standards only partially regulate the principles of safe creation, testing and use of AI, and standards in this area are still being created.

American doctrine also advocates the view that a physician must always inform the patient about using an artificial intelligence system. They

²⁰ Ibid.

²¹ The Food and Drug Administration is the authority responsible for the control and safety of drugs, supplements, cosmetics, medical devices, foods and biological materials in the United States. See: <https://opieka.farm/fda/>.

²² Cohen, "Informed Consent," 1443.

should explain the basic application of the technology and the basic nature of the algorithm. Moreover, they are obliged to clearly distinguish the roles that individual people will play during each part of the procedure from the roles played by artificial intelligence, a robotic system or a device.²³ Researchers dealing with medical law in the field of clinical trials also indicate that participation in an AI clinical trial without information can infringe on patient's right to self-determine who and what is involved in their care. At present, it is reasonable to assume that only humans, not AI systems, are involved in making their treatment decisions. However, many AI systems can now make human-like decisions that patients may reasonably expect to be made by clinicians.²⁴ Undoubtedly, it should be agreed that the patient should be informed only about the basics of how AI works, because explaining the technological details of the system's operations may negatively affect their decision-making process. Too much information can leave the patient confused. It is also important to let them know that the software will not work independently. There are two options for physician interaction with the system. The first is to determine the scope of activity, and the second is to support the AI in performing activities.

At the beginning of the analysis of the law in force in the EU Member States, it is necessary to point out the content of the draft Act on Artificial Intelligence. According to Article 52, healthcare providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that the AI system, the provider itself or the user informs the natural person in a timely, clear and intelligible manner that they are interacting with an AI system unless this is obvious from the circumstances and the context of use.²⁵ At this point, it is worth mentioning Belgian legislation. According to Article 8(2) of the Belgian Act on Patient's Rights, the information provided to the patient, necessary for consent,

²³ Daniel Schiff and Jason Borenstein, "How Should Clinicians Communicate With Patients About the Roles of Artificially Intelligent Team Members?," *AMA Journal of Ethics* 21, no. 2, (February 2019): 140.

²⁴ Subha Perni et al., "Patients Should Be Informed When AI Systems Are Used in Clinical Trials," *Nature Medicine* 29 (2023): 1891, <https://doi.org/10.1038/s41591-023-02367-8>.

²⁵ Amendments adopted by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021)0206 – C9–0146/2021 – 2021/0106(COD)).

concerns the purpose, nature, degree of urgency, duration, frequency, contraindications, side effects and risks related to the procedure that are important for the patient, the need for further care, possible alternatives and financial implications. The information also covers the possible consequences in the event of refusal or withdrawal of consent and other circumstances considered important by the patient or physician, including the legal provisions that must be respected in relation to the intervention. The literature indicates that a physician cannot omit information provided in Article 8 of the Act on Patient Rights if they use an artificial intelligence system. The information provided to the patient must be the same as if the doctor used methods not based on the operation of artificial intelligence systems. This does not mean that the patient should be informed about the use of AI or how it works.²⁶ Wannes Buelens points out that artificial intelligence and robots must be seen only as tools in the hands of a physician to provide health care, just like a scalpel or an MRI scanner. Generally, a physician is not obliged to inform a patient about every tool they use during treatment. The mere failure to inform the patient about the use of AI does not make them negligent if they provide the patient with information about their condition, prognosis, suitable health behavior, the purpose and nature of the treatment, significant risks and possible alternatives.²⁷

The Polish legislator and case law have not indicated the scope of information that a patient should be given by a physician when undergoing treatment with the use of artificial intelligence. This problem was raised in the *White Paper of AI in Clinical Practice*, which is a self-regulation of medical facilities regarding artificial intelligence.²⁸ This document indicates that it is not the mere fact of using artificial intelligence that makes

²⁶ Wannes Buelens, “Robots and AI in the Healthcare Sector: Potential Existing Legal Safeguards against a(n) (Un)justified Fear for ‘Dehumanisation’ of the Physician-Patient Relationship,” in *Artificial Intelligence and the Law*, eds. Jan De Bruyne and Cedric Vanleenhove (Cambridge: KU Leuven Centre for IT&IP Law Series, Intersentia, 2021), 560.

²⁷ *Ibid.*, 561.

²⁸ This document was created by the Polish Federation of Hospitals, the AI in Health Coalition and the working group on artificial intelligence, and constitutes self-regulation of medical facilities in the field of artificial intelligence. The document has been approved by the government and is published on the government portal gov.pl, and the meetings of the scientific council were attended by the Director of the Department of Innovation at the Ministry of Health and the Deputy Director of the Department of Innovation at the Ministry of Health;

it necessary to inform and receive consent from the patient, but its importance in the process of treatment and diagnosis. The authors point out that if AI were only a minor factor among many other ones (e.g. the use of a “smart” thermometer as part of a transplant procedure), providing information about it would not seem necessary, as it should not be a factor influencing the decision of the average patient. However, the situation is different when AI has a significant impact on the process or nature of the health service provided – the patient should know and understand this impact, otherwise, their consent may be questioned.²⁹ If the medical professional agrees with the decision taken by AI on the treatment method and communicates this to the patient, it is necessary to inform the patient about the role of artificial intelligence.³⁰ This solution seems correct. Informing the patient about the characteristics of each tool used to provide health services is pointless. Contrary to expectations, too much information provided to the patient reduces, rather than increases, awareness of their medical situation and the proposed treatment. Therefore, the patient should receive from the physician, even when using AI, only information that is important in the decision-making process to undergo treatment. This solution complies with case law, doctrine and standards functioning in the medical community.

The soft law developed in Poland by the medical community does not specify what information should be provided to the patient to obtain their consent. This problem was analyzed by German researchers at the University of Ulm. They created guidelines that can be successfully applied within the European Union countries and beyond the UE, including the USA. In the researcher’s opinion, eight new pieces of information should be added to the information classically provided to the patient, i.e. they should describe the input and output data of the AI, explain the AI training method and how it generates output data by learning from examples, explain the risks of cyber attack, algorithmic error and algorithmic mismatch (false

access to the document: https://aiwzdrowiu.pl/wp-content/uploads/2022/06/BIA_A-KSIE_GA_AI-W-ZDROWIU_2022.pdf.

²⁹ Paweł Kaźmierczyk, ed., *Biała Księga AI w praktyce klinicznej* (Warsaw: AI w zdrowiu, GRAI, PFSZ, 2022), 45, accessed May 17, 2024, https://aiwzdrowiu.pl/wp-content/uploads/2022/06/BIA_A-KSIE_GA_AI-W-ZDROWIU_2022.pdf.

³⁰ *Ibid.*

positive or false negative results), inform the patient of the right to a second opinion from a qualified physician and make the patient aware of how their data will be used outside the treatment process. The last element is the disclosure that the algorithmic decision will be taken without a physician's supervision.³¹ Currently, the operation of AI systems uncontrolled by a human physician is allowed in the USA, but EU countries will not provide such a possibility according to the draft of the act on artificial intelligence.

It needs to be stressed that the risk of algorithmic error may result from the fact that algorithms sometimes contain racial biases because their training datasets are not representative and therefore do not take into account gender, race, ethnicity and other differences. There is also the risk of overfitting, which occurs when the underlying datasets are too homogeneous and therefore prone to generalization problems. Patients should be informed about possible errors in the training datasets and how these may affect the results of AI processes.³²

The proposal of German researchers deserves approval. Providing the above information will enable the patient to make a conscious decision. It will also help avoid placing too much trust in AI and prevent patients from unjustified aversion to new technologies. Consent will be considered informed when the information is provided in a language accessible to the patient and adapted to their cognitive abilities. Providing correct information requires knowledge of the artificial intelligence system which the physician wants to use in the diagnostic and treatment process.

5. Conclusions

The above considerations lead to the following conclusions:

- 1) The use of AI systems to provide information and obtain consent for treatment would require an amendment to the current regulations. However, this is not justifiable given the key role of the relationship between the physician and the patient in the treatment process.

³¹ Franc Ursin et. al., "Diagnosing Diabetic Retinopathy With Artificial Intelligence: What Information Should Be Included to Ensure Ethical Informed Consent?," *Frontiers in Medicine* 8 (July 2021): 5, <https://doi.org/10.3389/fmed.2021.695217>.

³² *Ibid.*, 4.

- 2) To information normally given to the patient, the physician should add: a description of the AI input and output data, an explanation of how the AI is trained and how it generates output data by learning from examples, a description of the risk of a cyberattack, a description of the risk of algorithmic error, a description of the risk of algorithmic mismatch (false-positive or false-negative results), indicating the patient's right to a second opinion of a qualified physician, indicating whether and how the patient's data will be used outside the treatment process, the disclosure that algorithmic decision will be supported without the supervision of a physician (if it is possible).
- 3) The information indicated in point 2 should be provided to the patient only when the AI has a significant impact on the process or nature of the health service provided – the patient should know and understand this impact, otherwise the awareness of their consent may be questioned.
- 4) When a physician intends to use a tool equipped with AI only as an aid, e.g. a thermometer or a blood pressure monitor, the patient does not have to be informed about this, because in the mass of irrelevant data, they might not understand the issues that are of relevance for them.

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