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## **LIABILITY FOR MEDICAL ERROR INVOLVING ARTIFICIAL INTELLIGENCE IN DIAGNOSIS – A REGULATORY GAP IN POLISH MEDICAL LAW**

### **Abstract**

The development of artificial intelligence (AI) technologies in healthcare presents Polish medical law with a range of new normative challenges. This is particularly evident in matters concerning liability for diagnostic errors involving clinical decision support systems based on AI. The aim of this article is to analyse situations in which a physician relies on an AI system in the diagnostic process, which results in patient harm. In such cases, it remains unclear whether liability should be attributed to the physician, the entity providing the technology, the manufacturer, or the healthcare institution. Current Polish legal frameworks do not offer explicit regulations in this regard, and the absence of a statutory definition of medical error only intensifies this uncertainty.

The article reviews existing provisions of Polish civil law, with selected references to administrative regulations, in order to demonstrate the need for new norms addressing responsibility in human-algorithm interaction. It also examines key issues such as the physician's duty to inform the patient about the use of AI and the legal implications of obtaining informed consent.

The article concludes with recommendations aimed at facilitating a structured legal and ethical debate on the creation of a coherent medico-technological liability model within the Polish legal system. Without such reforms, both physicians and patients are left exposed to legal ambiguity, which may undermine trust in emerging technologies.

**KEYWORDS**

physician liability, artificial intelligence, medical law, medical error, informed consent, algorithmic ethics

**SŁOWA KLUCZOWE**

odpowiedzialność lekarza, sztuczna inteligencja, prawo medyczne, błąd medyczny, świadoma zgoda, etyka algorytmiczna

**I. ARTIFICIAL INTELLIGENCE AS A NEW FACTOR  
IN THE MEDICAL DECISION-MAKING PROCESS**

The introduction of artificial intelligence (AI) into medical practice is transforming the traditional model of liability, which has historically been based on a binary doctor-patient relationship. Diagnostic algorithms, particularly those based on machine learning, function as automated clinical decision support systems (CDSS) whose involvement effectively co-determines diagnosis and, indirectly, treatment. From the perspective of legal theory, this technology does not meet the criteria of a classical legal subject, as it lacks consciousness, intention, and the capacity to bear responsibility in the normative sense. Accordingly, AI, as a tool, cannot be regarded as a legal subject liable for its actions, but rather as a causative factor necessitating a reinterpretation of how fault, harm, and causation are attributed in the context of automated processes.<sup>1</sup>

From a doctrinal perspective, however, the introduction of AI has not resulted in any formal transformation of the normative model of liability. No legislative measures have modified the classical structure of fault-based or contractual liability under the Civil Code, meaning that physicians continue to bear responsibility under Articles 415, 471 and 430 CC, depending on the circumstances. What is changing is not the legal construction of liability, but the factual and cognitive context in which the physician operates. Although the prevailing view rejects the idea that AI systems may possess legal subjectivity, a minority strand of scholarship argues in favour of recognising at least limited or functional legal agency in autonomous systems.<sup>2</sup> Such views, although not accepted in Polish

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<sup>1</sup> Thomas Nagel, *Mortal Questions* (Cambridge University Press 1979).

<sup>2</sup> David C Vladeck, 'Machines without Principals: Liability Rules and Artificial Intelligence' (2014) 89(1) *Washington Law Review* 117–180; Samir Chopra and Laurence F White, *A Legal Theory for Autonomous Artificial Agents* (University of Michigan Press 2011); Paweł Księżak,

law, are important for comparative purposes and illustrate the conceptual tensions at the boundary between human and algorithmic action.

It is noted in the literature that traditional models of liability – particularly tort liability – are grounded in the premise of human agency and the ability to foresee the consequences of one’s own actions.<sup>3</sup> Meanwhile, decisions involving AI may at times surpass the understanding of the physician, particularly when algorithms operate as opaque systems (the so-called black box AI) and rely on statistical correlations whose internal logic remains cognitively inaccessible to the user. This issue is compounded by the fact that automated decision-making systems may produce outcomes that are discriminatory or erroneous in a non-material, undetectable manner, lacking signals recognisable to human perception. Unlike classical cases of discrimination, automated determinations do not provide affected individuals with clear grounds to identify the source of the error, making it difficult not only to demonstrate harm but also to invoke existing legal remedies. As a result, the boundaries between human responsibility and responsibility ‘embedded’ within the technical system architecture become blurred, leading to a liability gap and necessitating a fundamental rethinking of current normative categories.<sup>4</sup>

Importantly, the difficulty lies not in the blurring of responsibility as such, but in the evidentiary barriers to demonstrating breach of duty or causal connection. This challenge has been widely discussed in the context of ‘black-box medicine’, meaning diagnostic systems whose internal logic cannot be reproduced or understood even by their developers.<sup>5</sup> In such cases, the physician may be unable to meaningfully verify AI outputs, which complicates the fulfilment of the standard of due diligence.

At the regulatory level, Article 13(1) of the AI Act requires high-risk AI systems, including diagnostic tools, to be designed ‘in a way that ensures sufficient transparency to enable deployers to interpret a system’s output’. While this obligation marks an important shift, practical implementation remains uncertain,

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‘Zdolność prawna sztucznej inteligencji (AI)’ in Włodzimierz Robaczyński (ed), *Czynić postęp w prawie* (Łódź 2017) 67–84; Marlena Jankowska, ‘Podmiotowość prawna sztucznej inteligencji’ in Agnieszka Bielska-Brodziak (ed), *O czym mówią prawnicy, mówiąc o podmiotowości* (Katowice 2015).

<sup>3</sup> Herbert LA Hart, *Punishment and Responsibility* (OUP 1968); Joel Feinberg, *Doing and Deserving* (Princeton University Press 1970).

<sup>4</sup> Sandra Wachter, Brent Mittelstadt and Chris Russell, ‘Why Fairness Cannot Be Automated: Bridging the Gap Between EU Non-Discrimination Law and AI’ (2021) 41(1) *Computer Law & Security Review* 105567.

<sup>5</sup> William Nicholson Price II, ‘Regulating Black-Box Medicine’ (2017) 116(3) *Michigan Law Review* 421–474.

particularly in systems relying on deep learning architectures that inherently lack interpretability.

In medical practice, algorithmic discrimination may take the form of systematically lower sensitivity of detection in certain demographic groups (e.g., women, racial minorities), biased training data, or non-uniform error distribution. Such failures may not be perceptible to physicians, yet may produce unequal access to accurate diagnostics. The legal system does not yet provide explicit mechanisms to address these subtler forms of algorithmic harm.

In such cases, the question arises as to whether the role of the physician as the sole decision-maker should be redefined. Contemporary scholarship increasingly suggests that medical decision-making constitutes the output of a socio-technical decision system in which the physician is only one component – often the final one, but not necessarily the dominant one.<sup>6</sup> This perspective reflects a reality in which diagnostic outcomes emerge from an interaction between human clinical judgement and algorithmic processes that embody their own epistemic assumptions, data-driven inferences, and embedded value choices. As Virginia Dignum argues, contemporary AI systems operate not as passive tools but as active participants in socio-technical environments, capable of shaping classification, inference, and recommendation processes in ways that have moral and legal significance.<sup>7</sup>

Such an environment challenges the classical model of fault, which presupposes a clear link between a human agent's conduct and the harmful outcome. When an AI system generates outputs that substantially influence clinical reasoning, the physician's fault may no longer be the sole or even primary source of error. However, this does not mean that responsibility becomes 'distributed' in an undifferentiated manner. Instead, several actors bear responsibility on different legal bases: the physician under Articles 415 and 471 of the Polish Civil Code (general tort and contractual liability), the manufacturer under Article 449<sup>1</sup> (product liability for defective devices or software), and healthcare entities under Articles 415, 416, 429 and 430 (organisational fault, liability for subordinates, and for the use of technical equipment).<sup>8</sup> Although the precise statutory provisions differ

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<sup>6</sup> See Luciano Floridi, Josh Cows, 'A Unified Framework of Five Principles for AI in Society' (2019) Harvard Data Science Review; Virginia Dignum, *Responsible Artificial Intelligence* (Springer 2019); Sandra Wachter, Brent Mittelstadt, 'A Right to Reasonable Inferences?' (2019) Columbia Business Law Review.

<sup>7</sup> Dignum *ibid* 2019.

<sup>8</sup> See the Polish Civil Code: Articles 415, 416, 429, 430 and 449<sup>1</sup>, as well as Article 471 in conjunction with Article 474.

across continental legal systems, the underlying principles of attribution remain analogous.

A useful comparison may be drawn with traditional medical devices not equipped with AI. In such cases, courts routinely separate the physician's duty of diligence from the manufacturer's duty to ensure the product's safety and from the healthcare entity's duty to organise healthcare services properly. As Bączyk-Rozwadowska notes, the introduction of AI does not replace these legal categories but transforms the factual context in which they operate by introducing new epistemic and evidentiary complexities.<sup>9</sup> Consequently, what requires re-evaluation is not the structure of civil liability itself but the criteria for assessing fault, causation, and verification duties in environments where human and algorithmic actors jointly influence clinical outcomes.

## II. MODELS OF ATTRIBUTING RESPONSIBILITY IN THE HUMAN-ALGORITHM ENVIRONMENT

Doctrinal discussions have introduced key models for assigning legal responsibility for errors arising from the operation of AI systems in medicine. As noted by Cestonaro and others (2023), the lack of algorithmic transparency and the limited ability of humans to interfere with AI-generated recommendations may place the physician in a position where they act primarily as an executor of system suggestions, with limited ability to independently verify their correctness.<sup>10</sup> In such circumstances, concentrating full responsibility on the physician is disproportionate and inconsistent with principles of procedural fairness.

For this reason, the authors propose a model of distributed responsibility, in which obligations are allocated among several actors involved in the lifecycle of an AI system: the physician, the software developer, the algorithm designer, and the healthcare entity deploying the technology. According to this proposal, the physician is responsible for the correct use of the system and for exercising due diligence; the developer is accountable for ensuring that the product meets applicable legal and technical requirements; and the healthcare entity is responsible for supervision, staff training, and safe implementation.<sup>11</sup>

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<sup>9</sup> Kinga Bączyk-Rozwadowska, 'Civil liability for damages caused in connection with the use of artificial intelligence in medicine' (2021) 3–4(8) PPrMed.

<sup>10</sup> Clara Cestonaro and others, 'Defining medical liability when artificial intelligence is applied on diagnostic algorithms' (2023) 10 *Frontiers in Medicine* 1305756.

<sup>11</sup> *Ibid.*

This proposed model differs from the currently applicable legal framework, in which liability is not ‘distributed’ but actor-specific. Under Polish law, each stakeholder bears responsibility under different legal bases:

- the physician under Articles 415 and 471 of the Polish Civil Code (general tort liability and contractual liability for failure to exercise due care),
- the manufacturer under Article 449<sup>1</sup> of the Civil Code and, at the EU level, under Directive (EU) 2024/2853 on liability for defective products, which establishes strict liability for placing unsafe or defective AI-based medical devices on the market,<sup>12</sup>
- the healthcare entity under Articles 415, 416, 429 and 430 of the Civil Code (organisational fault, liability for subordinates, and liability for defective equipment used in the treatment process).<sup>13</sup>

While the statutory foundations of liability remain unchanged, the emerging distributed responsibility model draws attention to the need to conceptualise responsibility across all stages of the AI system lifecycle – from design and validation to deployment and routine clinical use – and to recognise that harm may result from interactions between multiple actors rather than from a single identifiable fault.

Additionally, several authors have proposed introducing no-fault compensation schemes as an alternative or complement to traditional fault-based medical liability, drawing in particular on the long-standing Scandinavian patient-injury systems.<sup>14</sup> These systems – most notably the Swedish Patient Injury Act (2010:1128) and the nationwide patient insurance scheme administered by LÖF – provide compensation for preventable or system-related medical injuries without requiring proof of individual fault.<sup>15</sup> Similar mechanisms operate in Denmark under the Patient Compensation Act, which awards compensation based on criteria such as avoidability, system adequacy and expected standard of care.<sup>16</sup> According to comparative analyses, these models could offer an effective response to harms

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<sup>12</sup> Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products, repealing Directive 85/374/EEC (OJ L 2024/2853).

<sup>13</sup> Act of 23 April 1964 – Polish Civil Code (Journal of Laws 1964 No 16 item 93, as amended), Arts 415, 416, 429, 430 and 449<sup>1</sup>, and Art 471 read together with Art 474.

<sup>14</sup> Anne-Maree Farrell, Sarah Devaney, Amber Dar, ‘No-Fault Compensation Schemes for Medical Injury: A Review’ (SSRN Scholarly Paper No 2221836, 2013) <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2221836](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2221836)>.

<sup>15</sup> Swedish Patient Injury Act (Patientskadelag 2010:1128); LÖF – The Swedish Patient Insurance (official national insurer for patient injuries) <<https://lof.se>>.

<sup>16</sup> Danish Patient Compensation Act (Consolidation Act No 995 of 14 June 2018).

caused by AI-supported diagnostics, especially where algorithmic opacity makes it impossible to identify a culpable actor.<sup>17</sup>

The justification for such proposals lies in the need to preserve patient trust, reduce evidentiary burdens and adapt compensation mechanisms to the epistemic complexity of machine-learning systems. Furthermore, scholars emphasise the importance of developing standardised evidentiary tools for assessing algorithmic malfunction. Wachter, Mittelstadt and Russell propose ‘conditional demographic disparity’ (CDD) metrics to identify discriminatory or anomalous system behaviour without abandoning contextual judicial reasoning.<sup>18</sup>

Whether a no-fault scheme could be adopted in Poland depends on political willingness to create a publicly financed patient-injury fund similar to the Swedish and Danish schemes. Although the concept aligns with ongoing debates about improving access to compensation for medical harm, its implementation would require significant institutional reforms, clear coordination with existing tort mechanisms and a stable financing structure.

As Daniel Schönberger observes, AI is regarded as the most transformative technology of the 21<sup>st</sup> century, with healthcare being one of its earliest areas of application. The implementation of AI technologies in diagnosis and treatment not only holds the potential to improve service quality and ease the burden on medical staff, but also brings significant legal and ethical risks that require detailed regulation.<sup>19</sup>

### III. MEDICAL ETHICS AND THE USE OF AI – BETWEEN DUE DILIGENCE AND DELEGATION

From the perspective of medical ethics, the use of AI generates tension between the duty to act in accordance with current medical knowledge (*lex artis*) and the risk of excessively delegating responsibility to non-human systems. Article 4 of the Code of Medical Ethics (KEL) imposes an obligation on physicians to act in

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<sup>17</sup> Farrell and others (n 14) 14–22.

<sup>18</sup> Sandra Wachter, Brent Mittelstadt, Chris Russell, ‘Why Fairness Cannot Be Automated: Bridging the Gap Between EU Non-Discrimination Law and AI’ (2021) 41 *Computer Law & Security Review* 105567.

<sup>19</sup> Daniel Schönberger, ‘Artificial Intelligence in Healthcare: A Critical Analysis of the Legal and Ethical Implications’ (2019) 27(2) *International Journal of Law and Information Technology* 171 <<https://doi.org/10.1093/ijlit/caz004>> accessed 4 May 2025.

accordance with the current state of medical science and to critically evaluate sources of information.<sup>20</sup> A parallel obligation is formulated in Article 4 of the Act on the Profession of Physician and Dentist, which requires the physician to provide healthcare with due diligence and in accordance with professional knowledge and ethical principles.<sup>21</sup>

However, when an AI system functions as a non-transparent ('black-box') tool and offers no real possibility for the physician to verify how the output was generated, the question arises whether the physician can be held fully accountable for the consequences of its use. In principle, this concern should be mitigated within the European Union, as Article 13 of the AI Act requires high-risk AI systems to be designed and developed in such a way that their operation is sufficiently transparent to enable users – including physicians – to interpret the output appropriately.<sup>22</sup> Nonetheless, significant practical challenges persist, as physicians often lack access to documentation, training, or technical competence necessary to understand algorithmic behaviour, leaving the boundaries of responsibility uncertain in AI-supported clinical environments.

Ethicists such as Luciano Floridi and James Moor argue that autonomous systems should be understood as quasi-moral agents, which justifies introducing a new ethical category of systemic responsibility, in which duties are distributed and shared across all actors involved in the design and use of an AI system.<sup>23</sup> In this view, the physician continues to bear responsibility for the decision to use the AI system in a particular clinical context, but not necessarily for what may be termed a technical error.

In the context of medical AI, a technical error refers to a malfunction, defect or improper operation of the system as a technological product – for example, training-data defects, software bugs, hardware malfunction, incorrect integration with hospital IT infrastructure, or erroneous output caused by faulty algorithms. Such errors fall within the domain of product liability (Article 449<sup>1</sup> of the Polish Civil Code) or warranty for defects under general civil law, rather than within the scope of the physician's *lex artis* obligations.<sup>24</sup> From a legal perspective, therefore,

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<sup>20</sup> Kodeks Etyki Lekarskiej (14 December 1991) <<https://sip.lex.pl/akty-prawne/akty-korporacyjne/kodeks-etyki-lekarskiej-286454095>> accessed 6 May 2025.

<sup>21</sup> Act of 5 December 1996 on the Profession of Physician and Dentist (Journal of Laws 2023, item 1516), Art 4.

<sup>22</sup> Regulation (EU) 2024/1689 (Artificial Intelligence Act), Art 13(1).

<sup>23</sup> James H Moor, 'The Nature, Importance, and Difficulty of Machine Ethics' (2006) IEEE Intelligent Systems; Luciano Floridi and Josh Cows, 'A Unified Framework of Five Principles for AI in Society' (2019) 5 Harvard Data Science Review 1.

<sup>24</sup> Act of 23 April 1964 – Polish Civil Code, Arts 449<sup>1</sup>–449<sup>10</sup> (product liability) and Arts 556–576 (warranty for defects).

the physician may be responsible for the use of the system but not for defects inherent in the system itself, which should be attributed to the manufacturer or the entity responsible for deploying the technology.

At the same time, Floridi and his team proposed a framework of five ethical principles that should form the foundation for designing and deploying artificial intelligence: beneficence, non-maleficence, autonomy, justice, and explicability. The latter concept combines the understandability of a system's operation with the assignability of responsibility, which is crucial for ensuring the responsible use of AI in clinical practice.<sup>25</sup>

#### **IV. PATIENT CONSENT AND THE DUTY TO INFORM IN THE CONTEXT OF AI**

A key issue from the perspective of patients' rights is the lack of regulation concerning the obligation to inform about the use of AI. The Act on Patients' Rights and the Commissioner for Patients' Rights (Articles 9–16) imposes on the physician the duty to obtain informed consent, which should be preceded by accurate and comprehensive information about the diagnostic and therapeutic methods applied.<sup>26</sup>

Since 2025, this issue has gained an additional dimension due to the new wording of Article 12 of the Code of Medical Ethics, which explicitly obliges physicians to inform patients about the use of artificial intelligence algorithms and prohibits the use of such tools in a way that limits the patient's awareness of possible therapeutic alternatives. At the same time, obligations arising from the AI Act impose duties not only on providers, but also on deployers of AI systems – including healthcare institutions.<sup>27</sup> In particular, Article 4 of the AI Act requires deployers to ensure a sufficient level of AI literacy among their staff, meaning adequate knowledge, training, and competence necessary to understand, operate and appropriately interpret the outputs of AI systems. A lack of such competencies, combined with the failure to disclose the algorithm's role in the clinical decision-making process, may result not only in a breach of the patient's right to informed consent, but also in the undermining of the ethical foundations of the medical profession.<sup>28</sup>

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<sup>25</sup> Floridi and Cowlis (n 23).

<sup>26</sup> Act of 6 November 2008 on Patients' Rights and the Commissioner for Patients' Rights (Journal of Laws 2009 No 52 item 417, as amended) Arts 9–16.

<sup>27</sup> Kodeks Etyki Lekarskiej (14 December 1991) <<https://sip.lex.pl/akty-prawne/akty-korporacyjne/kodeks-etyki-lekarskiej-286454095>> accessed 6 May 2025.

<sup>28</sup> Regulation (EU) 2024/1689 (Artificial Intelligence Act), Art 4.

## V. CURRENT LEGAL AND ETHICAL FRAMEWORKS FOR THE USE OF ARTIFICIAL INTELLIGENCE IN MEDICAL DIAGNOSTICS IN POLAND AND THE EUROPEAN UNION

Both the European Union and Poland have taken initial steps towards the normative regulation of artificial intelligence use in healthcare. The most important legal instrument at the EU level is Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024, known as the Artificial Intelligence Act (AI Act). It is the world's first comprehensive legal regulation on AI, which classifies systems according to risk levels and imposes obligations on their developers and users.<sup>29</sup>

From the perspective of medical law, particular importance is attached to the regulations concerning high-risk systems – including those used in imaging diagnostics, disease recognition, and clinical decision support. Although the main obligations arising from the AI Act will apply after the transitional period, as of 2 February 2025, provisions have already entered into force introducing, among other things:

- a prohibition on the use of AI in ways that pose an unacceptable risk, including manipulation of user behaviour or real-time remote biometric identification (Article 5);
- a requirement to ensure appropriate competencies of medical personnel working with AI, in accordance with Article 4 of the AI Act;
- the obligation to obtain approval from the person managing the medical facility before implementing an AI system.<sup>30</sup>

The Regulation also establishes the obligation to register, monitor and update the functioning of AI systems, which necessitates the implementation of appropriate internal procedures within healthcare facilities.

In parallel, ethical standards concerning the use of AI in medicine have been introduced in Poland. An amendment to the Code of Medical Ethics (CME), in force since 18 May 2024, introduced a new Article 12, which states that a doctor may use artificial intelligence systems in diagnostic, therapeutic and preventive activities, provided that the patient is informed, their informed consent is obtained, only certified tools are used, and the final clinical decision is made independently by the physician.

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<sup>29</sup> Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts [2024] OJ L237/1.

<sup>30</sup> *Ibid.*

The implementation of these principles is also supported by institutional efforts. The Centre for e-Health, within the framework of the Intelligent Services Platform (PUI) project, is developing certified AI models to support diagnostics, particularly in areas such as lung and breast cancer, ischaemic strokes, and X-ray pathology. This infrastructure is based on the assumption that AI functions as a clinical assistant rather than an autonomous decision-making entity. In response to the requirements of the AI Act, the Centre has also launched the CeZ Academy, through which doctors and administrative personnel are to acquire competencies related to the use of AI in accordance with current legal and ethical standards.<sup>31</sup>

The increase in the number of hospitals using AI – from 6.5% in 2023 to 13.2% in 2024 – indicates an urgent need for both education and stable regulatory frameworks that would allow doctors to act without fear of legal ambiguity in their decisions.<sup>32</sup>

## VI. REGULATORY GAP IN THE POLISH LEGAL FRAMEWORK

There is a lack of:

- a legal definition of medical error,
- regulations concerning the admissibility of using AI in diagnostics,
- norms specifying legal liability in cases of shared error (human-AI),
- and procedures for informing patients about the involvement of AI in decision-making.

The absence of these regulations leads to legal uncertainty, both for doctors and patients, and also makes it more difficult to pursue claims in the event of harm.

## VII. EMPIRICAL STUDY – THE USE OF ARTIFICIAL INTELLIGENCE IN MEDICAL DIAGNOSTICS FROM THE PERSPECTIVE OF CLINICAL PRACTICE

### 1. AIM AND OBJECTIVES OF THE STUDY

In order to verify theoretical findings regarding the legal and ethical aspects of using artificial intelligence (AI) in diagnostics, a qualitative empirical study was

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<sup>31</sup> Jacek Janik, 'PUI wykorzysta najnowsze technologie i AI' Warto wiedzieć (Termedia, 18 March 2025) <<https://www.termedia.pl/wartowiedziec/PUI-wykorzysta-najnowsze-technologie-i-AI,60842.html>> accessed 10 May 2025.

<sup>32</sup> Ibid.

conducted. Its aim was to identify real-world practices related to the application of AI in medical institutions and to diagnose issues concerning legal liability and the fulfilment of information duties towards patients.

The study was exploratory in nature and employed two complementary methods: an analysis of five clinical case studies in which AI tools were used in imaging diagnostics, and semi-structured in-depth interviews with three physicians (a radiologist, an internist, and a general practitioner) who use such technologies in their daily practice.<sup>33</sup>

## 2. CASE ANALYSIS RESULTS

The five analysed clinical cases highlight distinct patterns in how AI systems influence diagnostic processes and the allocation of responsibility among medical staff. Rather than serving merely as a technical aid, in each scenario the AI system shaped clinical reasoning in a different way – either by prompting additional verification, reinforcing clinical judgment, or generating discrepancies that required further investigation. The cases presented below illustrate these divergent dynamics and their legal-ethical implications.

### Case 1: Subtle lesion detected through AI and team-based assessment

In one of the provincial hospitals, an AI system was used to pre-select chest X-ray images. The algorithm flagged a potentially abnormal area in the lower lobe of the left lung. The radiologist, reviewing the AI indication, did not initially observe any clear signs of pathology; however, the alert prompted a more in-depth analysis. In consultation with a second specialist, a very subtle shadowing was identified, which, after further diagnostics, was confirmed as an early-stage lung cancer lesion. Due to timely intervention, rapid treatment was initiated, preventing further progression of the disease.

### Case 2: Unconfirmed AI suggestion and effective clinical verification

In a private diagnostic clinic, an AI system analysing CT scans of the abdominal cavity suggested the presence of a malignant lesion in the kidney. The physician did not ignore the algorithm's recommendation – he conducted a thorough review of the imaging data, supplemented with additional diagnostic tests and a consultation with an oncology specialist. After a comprehensive evaluation, no pathology was confirmed. The patient was informed about the use of AI in the diagnostic process, and the final decision was based on the physician's critical judgement.

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<sup>33</sup> Data were collected between March and June 2025, ensuring the anonymity of all participants.

### Case 3: Discrepancy between AI indication and clinical decision

At a clinical hospital, the AI system indicated a possible fracture of the L2 vertebra in a lumbar spine X-ray. The physician, doubting the algorithm's suggestion, ordered an MRI scan, which did not confirm the presence of a fracture. This case shows that AI can be a valuable early detection tool, but it does not replace independent clinical assessment and should be treated as a complement, not a substitute, for professional medical judgement.

In the remaining two cases, AI systems functioned effectively and aligned with the physicians' expectations. However, no documentation was found confirming that patients had given informed consent for the use of AI in the diagnostic process.

## 3. FINDINGS FROM PHYSICIAN INTERVIEWS

As part of the study, interviews were conducted with three physicians who have experience using AI tools across different diagnostic areas. The key findings are summarised below:

- All respondents indicated that they do not understand the precise functioning of the AI systems they use. One physician described AI as a 'black box that cannot be controlled'.
- Physicians admitted that they lack clarity regarding who holds responsibility in the event of a clinical error based on AI recommendations. As one radiologist put it: 'I feel like, formally, everything falls on me, but the system can be wrong too – so what then?'
- None of the respondents used separate consent forms specifically for AI use. They noted that 'no one requires it' and that the system 'is treated like any other diagnostic aid'.
- Younger physicians tended to place greater trust in AI systems, while older doctors approached them with more caution, stating that they use AI tools only in a supportive capacity.

## 4. STUDY CONCLUSIONS

The empirical study reveals significant discrepancies between the current legal and ethical framework – particularly Article 12 of the Medical Code of Ethics and the provisions of Regulation 2024/1689 (AI Act) – and the actual practices of using artificial intelligence in Polish healthcare facilities.

Firstly, in the analysed cases, it was found that the legal requirements concerning the duty to inform patients about the use of AI were not being fulfilled adequately. Patients were not clearly informed about the involvement of algorithmic systems in diagnostic or therapeutic processes.

Secondly, there is a lack of consistent and systemic procedures for obtaining informed consent for the use of AI technologies. Where consent is obtained, it does not include details about the risks and limitations associated with machine-learning-based systems.

Thirdly, the allocation of responsibility for errors resulting from AI-supported clinical decisions remains unclear. Physicians report that they feel formally accountable for final decisions, even though the AI system's influence may be decisive and difficult to challenge.

Fourthly, medical facilities do not provide staff with access to algorithmic documentation or adequate training in interpreting AI-generated results, which limits their ability to critically assess the output.

The findings clearly indicate the urgent need to develop unified organisational standards and legislative solutions that clarify the principles of liability for the functioning of artificial intelligence systems in the context of medical error. Without their implementation, we can expect a growing risk of violations of patient rights and escalating competency conflicts in clinical practice.

## VIII. CONCLUSIONS

The theoretical analysis, supplemented by findings from the author's empirical research, leads to the conclusion that the current framework of national medical law in Poland does not adequately address the challenges posed by the growing application of artificial intelligence (AI) in medical diagnostics. This particularly concerns the lack of precise legal provisions regarding liability for errors involving AI systems, the absence of clear professional standards of diligence for physicians using such technologies, and the failure to legally mandate obtaining patients' informed consent for the deployment of AI in their care.

A fundamental preliminary step in proposing any new error category is to clarify the meaning of medical error within the existing Polish legal-doctrinal framework. In the literature, a medical error is generally understood as a breach of the required standard of professional diligence (*lex artis*) resulting in patient harm,

most commonly defined as an improper action or omission by the physician in the diagnostic or therapeutic process.<sup>34</sup> Although these definitions – widely cited in Polish doctrine and reflected in judicial reasoning – adequately capture traditional, physician-centred forms of malpractice, they do not account for situations in which harm arises from the interaction between human judgment and AI-based systems. As recent scholarship suggests, including the emerging concept of ‘verification error’ related to failures in supervising or interpreting AI-generated recommendations,<sup>35</sup> technological mediation introduces qualitatively new forms of risk that fall outside classical taxonomies.

For this reason, it is necessary to develop a statutory definition of medical error that includes the notion of cognitive-technological error: an error arising from the dynamic interplay between the clinician’s cognitive processes and the behaviour of an algorithmic system. Such a framework should distinguish between:

1. physician-related errors (medical errors *sensu stricto*),
2. systemic errors stemming from defects, bias or instability within the algorithm itself, and
3. hybrid or interactional errors that emerge at the boundary between human and machine decision-making.

Introducing these distinctions into statutory law would align Polish legislation with emerging theories of distributed and adaptive responsibility in healthcare AI and provide courts with analytical tools adequate for resolving disputes involving algorithmically mediated clinical decisions.

Simultaneously, the provisions currently articulated in Article 12 of the Medical Code of Ethics should be elevated to statutory level. In particular, the Act on Patients’ Rights and the Patient Ombudsman should be amended to include obligations to inform patients about the use of AI systems and to obtain their specific, informed consent. This consent must be based on accessible information about how the algorithm works, its function, limitations, and the potential implications of decisions supported or generated by the system. Only in this way can the principle of patient autonomy be meaningfully upheld in the evolving technological landscape of clinical practice.

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<sup>34</sup> Miroslaw Nesterowicz, *Medical Law* (11<sup>th</sup> edn, Toruń 2016); Kinga Bączyk-Rozwadowska in Ewa Bagińska (ed), *System of Medical Law* (CH Beck, Warsaw 2021), 227ff.; Zdzisław Marek, *Medical Error* (Kraków 1999); Mieczysław Sośniak, *Civil Liability of the Physician* (Warsaw 1977), 119ff.

<sup>35</sup> Katarzyna Wałdoch, ‘Verification Error and Supervision Error – New Types of Medical Errors Resulting from the Use of Artificial Intelligence Systems Occurring During the Provision of Health Services’ (2024) 1 SIT.

While Polish law already attributes responsibility to different actors under separate legal regimes – for example, physicians under Articles 415 and 471 of the Civil Code, healthcare institutions under Articles 416, 429 and 430, and manufacturers under the product liability regime of Articles 449<sup>1</sup>–449<sup>10</sup> – these mechanisms operate in parallel rather than as an integrated system. The current framework does not explicitly address situations in which harm results from the interaction between clinical judgement and AI-generated outputs, nor does it clarify how liability should be allocated when multiple actors contribute to an AI-assisted diagnostic pathway. For this reason, the development of legislative or organisational mechanisms that articulate a coherent, multi-layered allocation of responsibility is essential. Such a structure would not replace existing legal bases but would clarify their coordinated application in cases involving algorithmic support: physicians would remain liable for breaches of professional diligence within their cognitive capacity; healthcare entities for organisational failures, including inadequate staff training or oversight; and developers or manufacturers for defects or safety deviations in AI systems. Establishing this clarified framework would more accurately reflect the complex, interdependent nature of AI-mediated clinical decision-making and enhance transparency in the human-machine relationship in medical practice.

Another urgent recommendation is the establishment of unified professional diligence standards for the use of AI in diagnostics. Currently, physicians lack clear guidelines on when and to what extent they may rely on algorithmic systems, and when they are obliged to independently verify AI output. There is also no regulatory requirement to document the use of AI in the diagnostic process, which hampers both legal review and the pursuit of claims. Therefore, it is advisable that the Ministry of Health or the Supreme Medical Council develop binding recommendations that could serve as a reference point for courts and regulatory authorities.

In line with Article 4 of the AI Act and the training initiatives announced by Poland's e-Health Centre, the implementation of mandatory certified training for physicians using high-risk AI systems should be strongly considered. Such training should cover the fundamentals of algorithmic function, limitations, ethical and legal considerations, and practical aspects of using and documenting AI in clinical decision-making. Lack of such competencies increases the risk of diagnostic errors and potential infringements on patients' rights.

Finally, the establishment of a national registry of incidents involving AI in healthcare should be considered, modelled after existing systems for reporting adverse medical events. Data collected through such a registry could be used to improve AI system quality, inform legislative initiatives, and support governmen-

tal oversight. Additionally, it would provide an empirical basis for identifying best practices and flagging high-risk scenarios.

In summary, only a comprehensive legislative approach – addressing liability, informed consent, professional competence, and systemic oversight – will ensure that the use of artificial intelligence in clinical settings is safe, transparent, and consistent with the rule of law. Failing to address these challenges risks not only undermining the ethical foundations of medical law but also eroding public trust in healthcare institutions.

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