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LEGAL CHALLENGES IN THE ERA OF ARTIFICIAL INTELLIGENCE REGARDING PATIENTS' RIGHTS: LESSON FOR VIETNAMESE MEDICAL STUDENTS

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ABSTRACT

Background: *This article examines the legal challenges to protecting patients' rights arising from the growing use of artificial intelligence (AI) in healthcare in Vietnam. Patients' rights to bodily integrity, life, and health are firmly recognized in the Constitution, the Civil Code 2015, and the Law on Medical Examination and Treatment 2023. While Vietnam's legal framework has advanced by codifying professional medical ethics into binding legal obligations focused on patient safety, it has not yet adequately adapted to AI-related risks. Algorithmic errors, lack of transparency, data bias, and unequal access to AI-based healthcare threaten patient safety, autonomy, and equality. The article argues that legal reform is necessary to address accountability, transparency, and informed consent in AI-assisted medical practices.* ***Methods:*** *The study employs a doctrinal legal methodology to analyze Vietnamese laws governing patients' rights, including constitutional provisions and healthcare legislation. It also examines selected civil and criminal court judgments on medical malpractice to identify practical difficulties in enforcing patients' rights, particularly the burden of proving fault and causation. In addition, the research draws on comparative and interdisciplinary literature on AI, medical ethics, and legal accountability to assess how AI challenges traditional models of liability and informed consent within the Vietnamese legal context.* ***Results and Discussion:*** *The findings indicate that Vietnamese law provides a relatively comprehensive framework for protecting patients' rights, with the 2023 Law on Medical Examination and Treatment emphasizing patient safety and risk management. However, judicial practice limits the effectiveness of remedies because it relies heavily on medical expert opinions. In AI-assisted healthcare, three major challenges emerge: risks posed by algorithmic errors and opaque decision-making; increased inequality stemming from data bias, costs, and digital divides; and the absence of clear legal standards governing informed consent, which undermines patient autonomy. These issues indicate a regulatory gap between existing law and technological developments.* ***Conclusion:*** *Although Vietnam has strengthened legal protections for patients' rights, AI fundamentally disrupts traditional healthcare governance. The absence of AI-specific rules on accountability, transparency, and informed consent poses significant risks to patient safety and autonomy. Urgent legal reforms are needed to ensure that the use of AI in healthcare protects patients' rights and dignity.*

KEYWORDS: Artificial Intelligence, Legal Challenges, Patients' Rights, Vietnamese Medical Students.

1. INTRODUCTION

1.1. Background

The right to life, body, and health is a moral right closely connected to each person, a civil right in particular, and a human right overall – essentially inviolable (Nurbay, 2016). This right is especially important in healthcare, where a country's system is aimed at universal health coverage, ensuring everyone has equal access to services that protect their body, life, and health (Alison, 2016). However, when discussing rights to the body, life, and health in healthcare here, instead of focusing on analyzing these rights in relation to the obligations of medical facilities and medical pratictioners in Vietnam from a practical standpoint, this article affirms that, legally, both Vietnam's general and specific legal frameworks recognize patients' rights and establish mechanisms—through preventive and post-inspection methods—to uphold these rights. Overall, Vietnam's legal system has, to some degree, fulfilled this mission; however, doubts remain about whether patients truly have equal access to healthcare services under current enforcement mechanisms. Are healthcare providers consistently prioritizing patients' rights and interests when choosing the most suitable and cost-effective treatments? Are patients sufficiently informed to make their own decisions about continuing, stopping, or choosing alternative options that best suit their needs and those of their families? Will the post-inspection mechanism—claims for medical malpractice in Vietnam—effectively serve its purpose? This article does not aim to determine definitively whether the answer is yes or no, as there is no single answer that applies universally. A simple yes-or-no would be unfair to dedicated doctors who care for patients tirelessly, or to patients who may encounter adverse experiences when accessing medical care. Instead, this article objectively analyzes and concludes that Vietnam possesses a legal framework, from broad to specific provisions, that recognizes patients' rights and safeguards their bodies, lives, and health. Nonetheless, this legal structure faces significant challenges in the digital age, such as: issues related to equitable access for patients; mechanisms for controlling software medical devices including AI as an independent medical device; the necessity of establishing an appropriate oversight framework to build trust in medical facilities and medical officials when implementing AI in healthcare—with clear transparency about responsibility; and finally, challenges surrounding informed consent to enhance patients' right to self-determination (Wafaa el at., 2026).

2. METHODS

The article employs a doctrinal legal research methodology combined with an interdisciplinary analytical approach. First, the method of legal analysis and interpretation is applied to examine Vietnamese laws governing patients' rights, including the 2013 Constitution, the 2015 Civil Code, the 2023 Law on Medical Examination and Treatment, and relevant implementing decrees and circulars. This approach clarifies how patients' rights are legally recognized and protected within the current normative framework.

Second, the case study method is employed to analyze selected criminal and civil court judgments concerning medical malpractice and professional liability. These cases illustrate practical challenges in enforcing patients' rights, particularly in establishing medical fault and causation in compensation claims.

Third, the study adopts a comparative, literature-based approach by engaging with international scholarship on AI-related risks, medical ethics, and legal accountability in healthcare. This interdisciplinary perspective enables a critical assessment of how AI disrupts traditional liability structures and informed consent models, and how these challenges resonate within the Vietnamese legal context. By synthesizing doctrinal analysis with empirical judicial practice and comparative insights, the article provides a comprehensive evaluation of legal risks and regulatory gaps arising from the integration of AI into healthcare services.

3. RESULTS

3.1. Vietnamese Legal Framework for Recognizing Patients' Rights

3.1.1. Fundamental Rights of Private Individuals

The supreme legal document is the 2013 Constitution of the Socialist Republic of Vietnam, which recognizes the inviolable right to bodily integrity and protects the health rights of all Vietnamese citizens under Article 20 (National Assembly, 2013). Article 38 then affirms: (i) Everyone has the right to protection, health care, and equality in the use of health services; (ii) The State and society shall invest in the development of the people's health protection and care, implement universal health insurance, and adopt policies to prioritize health care for ethnic minorities, people in mountainous areas, islands, and areas with extremely difficult socio-economic conditions (National Assembly, 2013).

Inheriting the spirit of the 2013 Constitution, the 2015 Civil Code, as the Constitution of private law, recognizes the rights of civil law subjects and provides mechanisms for exercising those rights and measures for protecting them. Article 33 and Article 34 affirm the basic rights of private individuals, which include: (i) Rights to the body: Individuals have the inviolable right to their bodies, protected by law on health. No one may infringe on another person's body (National Assembly, 2015); and (ii) Right to health protection: Individuals have the right to be guaranteed health and physical safety. Measures related to a person's body and health must be agreed to by that person unless otherwise provided by law (National Assembly, 2015).

Detailing several articles of the Law on Medical Examination and Treatment 2023 (National Assembly, 2023), Decree No. 96/2023/ND-CP (The Government, 2023) clarifies patients' rights as outlined in the Law on Medical Examination and Treatment 2023, focusing on two main points. First, patients' rights are contrasted with the obligations of medical examination and treatment facilities and healthcare providers. Second, the process of safeguarding patients' rights emphasizes preventive measures and the development of criteria and mechanisms to prevent medical risks and accidents, with responsibilities clearly specified at both the organizational and individual levels.

Specifically, Article 4 of Decree 96/2023/ND-CP, which guarantees patient safety during medical examination and treatment, outlines the principles and requirements for ensuring patient safety, affirming:

1. Medical examination and treatment facilities shall implement measures to ensure patients' safety during all stages of the patient intake procedure, examining, treating, and caring for them;
2. Medical examination and treatment activities must adhere to professional procedures, technical guidance, and quality standards issued by the Ministry of Health;
3. All medical interventions must be performed within the scope of licensed expertise and appropriate for the patient's health condition.

Next, Article 8 of Decree 96/2023/ND-CP (Detailing emergency obligations) requires medical examination and treatment facilities to immediately accept and provide emergency care to patients in urgent situations; they must not refuse or delay emergency treatment for any reason related to administrative procedures, cost, or health insurance (The Government, 2023). Therefore, it can be confirmed that the "Right to life of patients" is given absolute priority, and this also establishes a clear legal basis for addressing acts of refusing emergency care in connection with Decree 117/2020/ND-CP (The Government, 2020) and Decree 124/2021/ND-CP (The Government, 2021). Both documents collectively govern sanctions in the health sector.

3.1.2. Equal access to healthcare and information

The principles of medical examination and treatment are also clearly outlined in Article 8 of the Law on Medical Examination and Treatment 2023, which states: (i) Equality, fairness, and non-discrimination against patients; (ii) Respect for the rights of patients; (iii) Ensuring patient safety; (iv) Timely and strict compliance with professional and technical regulations (National Assembly, 2023). The rights of patients are also affirmed, including: receiving quality medical examination and treatment appropriate to their actual condition; ensuring the safety of life, health, and body during medical procedures; and selecting medical facilities and practitioners in accordance with legal provisions (National Assembly, 2023). Notably, patients have the right to refuse medical examination and treatment and to leave medical facilities in accordance with the law (National Assembly, 2023).

Article 4 of the Law on Medical Examination and Treatment 2023 confirms the principles of medical examination and treatment: Respect and protect patients' rights; ensure that patients receive adequate, timely, and honest information about their health status, treatment options, and the costs of medical examination and treatment (National Assembly, 2023).

The right to access information to prevent accidents involving bodily integrity, life, and health—Patient safety and risk control—is outlined in Article 9 of the Law on Medical Examination and Treatment 2023.

1. Patients are informed about their health status, the methods and services of medical examination and treatment, and the prices of these services; they are instructed on how to self-monitor, care for themselves, and prevent accidents (Art. 9.1).
2. Patients receive medical examinations and treatments using safe methods appropriate to their disease status and health, as well as the conditions at the medical facility. In particular, Clause 2 of Article 9 is a key provision for ensuring patient safety and preventing professional mistakes, and it affirms patients'

right to be cared for safely and appropriately (Art. 9.2).

Next, Article 12 on "Rights of Patients" affirms patients' informed consent and autonomy in healthcare via right to access informations: Patients should be provided with complete, timely, and truthful information about their health status, diagnosis, treatment options, risks, disease prognosis, and medical costs; they should be consulted and given explanations that are clear and easy to understand before making decisions about medical examinations and treatments; and they have the right to refuse or terminate medical examinations and treatments in accordance with legal provisions.

In addition, Circular 07/2014/TT-BYT (code of conduct, non-discrimination) affirms patients' rights to equal access to healthcare and the right to receive timely and accurate medical information (Ministry of Health, 2014). Accordingly, civil servants and health officials must: (i) be polite, gentle, and respectful when communicating directly or indirectly through the media; (ii) ensure that the information exchanged aligns with the work content that agencies, organizations, and citizens need to guidance and answer; (iii) promote and guide people to strictly adhere to the unit's internal regulations, processes, and professional standards (Art. 5.1).

Civil servants and health officials must not: (i) Be authoritarian, bossy, harassing, delaying, indifferent, or cause difficulties for organizations and individuals; (ii) Deliberately prolong the time spent on official duties and tasks related to agencies, organizations, and individuals (Art. 5.2).

In particular, Article 6, titled "Conduct of civil servants and health officials in medical examination and treatment establishments," emphasizes the importance of strictly following the 12 Medical Ethics Articles (Promulgated together with Decision No. 2088/QD-BYT dated November 6, 1996, by the Minister of Health) (Ministry of Health, 1996). According to Circular 07/2014/TT-BYT, civil servants and health officials must: (i) be friendly and welcoming, and fully guide patients through the necessary procedures; (ii) perform initial patient classification and organize medical examinations in an orderly manner according to established priorities; (iii) maintain confidentiality and show respect for patients during examinations, and inform or explain the patient's health status or condition to the patient or their legal representative; (iv) carry out medical examinations, order tests, and prescribe treatments appropriate to the patient's condition and financial situation; (v) instruct patients or their legal representatives on the proper use of prescribed medicines, care routines, and monitoring disease progress, and schedule follow-up appointments if needed for outpatients; (vi) assist patients in quickly completing hospitalization procedures when necessary (Art. 6.2).

In case of inpatient treatment, civil servants and health officials must: (i) urgently arrange beds for patients and guide and explain the hospital's and department's rules and regulations; (ii) examine, investigate, detect abnormal developments, and address patients' needs; promptly explain the patient's or the patient's legal representative's questions and suggestions; (iii) provide health education and guide patients or their legal representatives in implementing the treatment and care regimen; (iv) promptly meet professional requirements; be available at the request of the patient or the patient's legal representative; (v) for patients indicated for surgery, notify and explain the disease condition, surgical methods, and possible risks to the patient or their representatives in advance, and fully carry out prescribed preparations. The reason must be clearly explained to the patient or the patient's legal representative when the surgery must be postponed or suspended (Art. 6.3).

For the patient who is discharged from the hospital or transferred: (i) Notify and instruct the patient or the patient's legal representative about what to do after discharge from the hospital. In the case of a transfer, explain the reason to the patient or the patient's legal representative; (ii) Publicize the details of each expense on the payment slip for medical services that the patient must pay; fully explain at the request of the patient or the patient's legal representative; (iii) Carry out procedures for patients to be discharged from the hospital or transferred as prescribed; (iv) Receive comments from the patient or the patient's legal representative when the patient is discharged from the hospital or transferred (Art. 6.4).

Therefore, the right to provide medical information has been clearly established and increasingly expanded, especially in the Law on Medical Examination and Treatment 2023. The law acknowledges the connection between information and consent and affirms the patient's right to self-determination, while also imposing a legal obligation on medical practitioners to explain and consult.

However, Vietnam's legal framework lacks uniform standards for the level and form of consent provision (Nguyen, 2026). Therefore, to realize the right to optimism, clear guidance from relevant ministries is needed (Nguyen, 2026). Practice also shows that awareness of and adherence to patients'

information rights remain uneven across medical examination and treatment establishments and across regions (Nguyen, 2025a). Therefore, in addition to detailed guidelines and regulations that unify the industry's general standards, it is necessary to legislate several patient rights, such as the right to access patients' medical records as an independent right, and to provide separate sanctions for providing incomplete information without direct consequences. It is also necessary to develop an independent mechanism to assess compliance with the obligation to provide patients with medical information (Nguyen, 2025a).

3.2. Law on mechanisms to ensure the rights of patients

The right to ensure the safety of patients' bodies and health has been officially transformed into a mandatory legal obligation for medical examination and treatment facilities, no longer limited to professional ethical standards. The obligation is also established as a risk-control measure. Therefore, Article 7 of Decree 96/2023/ND-CP (Provisions on responsibilities of medical examination and treatment establishments) provides a mechanism for risk control in medical activities. Accordingly, medical examination and treatment facilities must: (i) arrange sufficient qualified staff; (ii) ensure safe medical equipment and facilities; (iii) not perform medical examinations and treatments beyond their licensed scope.

When an incident affecting a patient's health and safety occurs, a medical facility shall: (i) promptly address and resolve it; (ii) notify and inform patients or their relatives as prescribed.

In addition to establishing the legal obligations of medical examination and treatment facilities and medical practitioners, the Decree outlines measures to prevent medical malpractice in Articles 5 and 6 of Decree 96/2023/ND-CP (Regulations on quality management and patient safety), with the following key points: (i) Medical examination and treatment facilities must: Develop and implement a quality management system; Establish procedures for identifying, reporting, analyzing, and addressing medical issues; and implement measures to prevent professional errors.

Decree 117/2020/ND-CP (Decree 117) and Decree 124/2021/ND-CP (Decree 124) are two key legal documents issued by the Vietnamese government that regulate sanctions for administrative violations in the healthcare sector. Decree 124/2021/ND-CP amends and adds to many articles of Decree 117/2020/ND-CP, including regulations on e-cigarettes, medical equipment price management, medical examination and treatment, health insurance, and other related areas, aiming to complete the legal framework for penalizing administrative violations in health and enhance the effectiveness of state management.

Specifically, it directly addresses the administrative responsibility of medical practitioners in conducting examinations and treatments to protect the legitimate rights and interests of patients' bodies, lives, and health, as outlined in Article 48 of Decree 117/2020/ND-CP. The following regimes are applied to enforce and promote patients' rights.

1. A warning or a fine ranging from VND 200,000 to VND 500,000 shall be imposed for one of the following acts: failing to respect patients' rights as prescribed by law (Art 48.1).
2. A fine ranging from VND 500,000 to VND 1,000,000 shall be imposed for one of the following acts: failing to comply with the internal rules of medical examination and treatment facilities; failing to give priority to medical examination and treatment for emergency cases, children under 06 years old, people with severe disabilities, individuals aged 80 and over, people with meritorious service to the revolution, and pregnant women (Art 48.2).
3. A fine ranging from VND 1,000,000 to VND 3,000,000 shall be imposed for one of the following acts: Failing to comply with the practitioners' code of conduct as prescribed by law; stigma and discrimination against patients (Art 48.3).

As an additional form of sanction, doctors and nurses who violate shall be deprived of the right to use the medical examination and treatment practice certificate for a period of between 01 and 03 months for the acts specified in; suspend the operation of part of the establishment (such as violating departments, centers, units, and divisions), or deprive the establishment of the right to use the license for medical examination and treatment activities (for violations affecting the entire operation of the medical examination and treatment establishment) for a period of from 01 month to 03 months (Art 48.7).

Thus, it is clear that for the first time, the Decree formalizes patient safety as a mandatory management requirement. It shifts the focus from simply managing responsibility after damage occurs to actively preventing medical risks. In this way, the legal framework enhances the organizational responsibility of medical examination and treatment facilities to protect patients' rights.

However, the regulations remain principled. Without the professional guidance of the Ministry of Health, it is difficult to fulfill the obligations prescribed by law, which require specific standards as measures, providing a framework of reference to confirm whether the medical examination and treatment facility has fulfilled its obligations correctly and fully (Nguyen, 2026). In particular, the enforcement mechanism is incomplete without an independent supervisory body for medical risk management (Nguyen, 2026). Additionally, there are no regulations governing patient autonomy in requesting specific safety measures, nor is there a mechanism for disclosing patient safety information (Nguyen, 2026).

3.3. Dispute resolution practices

Vietnamese legal practice concerning the responsibilities of medical examination and treatment facilities and medical practitioners when they breach their obligations (medical errors – medical malpractice) is clearly reflected in the civil, administrative, and criminal liability sections of the provided resources.

3.3.1. Criminal liability

Criminal liability typically occurs when violating professional or other regulations governing medical services leads to serious consequences, especially death. Violation of regulations on medical examination and treatment (Article 315 of the Criminal Code)

1. The first case: Judgment No. 14/2023/HS-PT, dated 29-6-2023, People's Court of BK province (Appellate Criminal Judgment, 2023).

Accordingly, Defendant Giang A S, who does not hold a medical practice certificate and lacks a recognized heirloom remedy, has examined and prescribed traditional medicine (including the Gelsemium elegans, which contains toxins such as alkaloids) for others based on personal experience. This behavior resulted in the death of a patient (Mr. Nong Van T2) due to alkaloid poisoning from the Gelsemium elegans. The Court found Defendant Giang A S guilty of the crime of "Violating regulations on medical examination and treatment" under Point a, Clause 1, Article 315 of the Criminal Code, and sentenced him to 15 months in prison, suspended, with 30 months probation. Additionally, he is banned from performing medical examinations and treatments, producing, dispensing, or selling drugs, or providing other medical services for 30 months (Appellate Criminal Judgment, 2023).

2. The second case: Judgment No. 45/2023/HS-ST, dated 7/31/2023, of the People's Court of District 6, Ho Chi Minh City (First-Instance Criminal Judgment, 2023).

Accordingly, Defendant Vo Trong H injected fillers into a woman at an establishment that was not licensed to operate as a medical facility. The defendant did not hold a practicing certificate and had no degree in pharmacology or medicine. As a result, the woman died from "Butt implant injection causing pulmonary embolism due to fat." The court concluded that Vo Trong H committed the crime of "Violating regulations on other medical services" under Point a, Clause 1, Article 315 of the Criminal Code. This act also violates administrative regulations on health insurance (Decree 117/2020/ND-CP). The judgment affirmed that Defendant Vo Trong H was sentenced to 01 year and 06 months in prison, with the sentence suspended, and ordered to pay a fine of 15,000,000 VND (First-Instance Criminal Judgment, 2023).

3.3.2. Civil Liability

Civil liability involves compensation for non-contractual damages that result from the activities of a medical facility or an independent medical practitioner. Its determination largely relies on the Professional Council's conclusion regarding whether a professional and technical fault occurred. Most cases suggest that Vietnamese courts now tend to reject compensation claims based on "medical malpractice." In civil lawsuits for damages to health or life, courts generally dismiss the plaintiff's claim if the Professional Council finds that both the medical facility and practitioner adhered to proper professional procedures and that no fault caused the damage.

1. The first case: Judgment No. 02/2019/DS-PT, dated 01/23/2019, of the People's Court of Quang Ninh Province, regarding "Disputes over medical examination and treatment". (Appellate Civil Judgment, 2019)

Dispute at V N plaintiff and T D Hospital: The plaintiff demanded compensation, claiming that the hospital was responsible for his child's congenital eye disease. The Ministerial Professional Council of the Ministry of Health determined that the entire process of monitoring, care, and treatment was carried out thoroughly and diligently, in accordance with professional standards and technical procedures. The hospital had no professional or technical faults, and the child's eye condition was confirmed to be congenital. The decision of the professional council established by the Ministry of Health is the final decision on whether any

professional or technical faults occurred. Since no violations or damages were identified, the claim was rejected (Appellate Civil Judgment, 2019).

2. The second case: Judgment No. 564/2024/DS-PT, dated June 21, 2024, of the People's Court of Ho Chi Minh City, concerning "Dispute over compensation for damage in the field of medical examination and treatment" (Appellate Civil Judgment, 2024a).

Accordingly, the dispute involved compensation for damages incurred during medical examination and treatment activities between the plaintiff, Ms. Le Thi H, and the defendant, T1 Hospital. Ms. H requested the hospital to compensate for both material and mental damages, totaling over VND 1.4 billion, following the deaths of her daughter and grandson. She accused the hospital of negligence and professional faults. However, based on the conclusion of the Professional Council of the Department of Health of Ho Chi Minh City, the Court of Appeal determined that T1 Hospital had properly adhered to professional procedures and that there was no causal link between the treatment process and the patients' deaths. Therefore, the Court did not accept the plaintiff's full lawsuit claim. Nonetheless, the Court acknowledged T1 Hospital's voluntary support for Le Hoang Anh G (the child of the deceased) in the amount of VND 250,000,000, and also amended the first-instance judgment to reflect this (Appellate Civil Judgment, 2024a).

3. The third case: No. 646/2024/DS – PT, dated 11/11/2024, from the People's Hanoi City Court regarding "Compensation for damages" (Appellate Civil Judgment, 2024b).

The dispute involves a claim for damages between the plaintiff, Ms. Nguyen Thi T, and the defendant, Thanh Nhan Hospital. Ms. T filed a lawsuit seeking VND 300,000,000 in compensation, claiming that the hospital caused a fracture of her left knee bone during laparoscopic surgery to clean the knee joint. However, after thoroughly reviewing the medical records, imaging results, and findings from the Professional Council of the Hanoi Department of Health, the court confirmed that there was no evidence that the hospital had fractured Ms. T's bones. As a result, the Court of Appeal did not accept Ms. T's appeal and upheld the judgment of the first instance (Appellate Civil Judgment, 2024b).

A notable aspect of resolving disputes arising from medical errors is the court's recognition of voluntary support: in civil cases, even without legal error, medical facilities may voluntarily provide financial assistance to the patient's family to ease their hardships, demonstrating compassion and ethical responsibility. For example, T1 Hospital supports Le Hoang Anh G with VND 250,000,000, and TN Hospital supports Ms. Nguyen Thi T with VND 60,000,000 (Appellate Civil Judgment, 2024b).

Internal handling of mistakes that do not lead to serious consequences may result in internal discipline. For example, at TN Hospital, two doctors were asked to review their actions, learn from the experience, and face disciplinary measures, including lowering their emulation rating, not grading, and being restricted from enjoying the benefits of the regime for an additional three months, due to shortcomings in recording medical records and failing to clearly explain to patients (Appellate Civil Judgment, 2024b).

4. The fourth case: Judgment No. 677/2022/DS-PT, dated 11/21/2022, of the People's Court of Ho Chi Minh City, concerning "Dispute over compensation for damage in the field of medical examination and treatment" (Appellate Civil Judgment, 2022a).

The appellate judgment addressed the case "Dispute over compensation for damage in the field of medical examination and treatment" between the plaintiff, Ms. Le Thi B, and the defendant, Q Joint Stock Company. The case involved the invasion of biological space following a dental restoration, specifically the porcelain crown-wrapping service at the defendant's clinic. The Appellate Trial Panel partially accepted Ms. B's appeal, ordering Q Joint Stock Company to pay the actual treatment costs and the cost of re-enveloping 36th teeth, totaling VND 13,020,056, but rejected other claims, such as the cost of a new porcelain wrapping or estimated severance pay. The final decision amended the first-instance judgment, clarifying the responsibility to compensate for actual damages arising from sequelae of medical examination and treatment (Appellate Civil Judgment, 2022a).

5. The fifth case: Judgment No. 30/2022/DS-PT dated 25-4-2022, of the People's Court of Binh Phuoc Province, regarding "Dispute over claim for non-contractual damage to life" (Appellate Civil Judgment, 2022b).

The plaintiff, Ms. Le Thi H, filed a lawsuit against the Health Center of District H, claiming that the doctor's prescription of an infusion and medication caused severe anaphylaxis (Grade II), which resulted in her child, Nguyen Le My D, dying. The Appellate Trial Panel accepted the plaintiff's appeal and decided to overturn the entire first-instance judgment because it found that the lower court had seriously violated procedural rules, including inadequate evidence collection and reliance on

conclusions from the Medical Professional Council that did not ensure objectivity and proper legal procedures. This appellate ruling orders that the case be sent back to the first instance for re-resolution in accordance with standard procedures, protecting the legitimate rights and interests of the parties involved (Appellate Civil Judgment, 2022b).

The Expert Council's conclusion is not the final, legally binding decision. The court can make the ultimate decision regarding the appropriateness, objectivity, and compliance with legal provisions (Appellate Civil Judgment, 2022b).

3.4. Administrative liability

Administrative liability involves penalizing violations of regulations regulating state management in the health sector, especially those concerning practice conditions and the operation of healthcare facilities.

1. Judgment No. 45/2023/HS-ST, dated 7/31/2023, of the People's Court of District 6, Ho Chi Minh City, regarding "Violation of Practice and Operation Conditions" (First-Instance Criminal Judgment, 2023).

In the criminal case of Vo Trong H, the Court documented the defendant's violations of Decree No. 117/2020/ND-CP on sanctions for administrative violations in the health sector, specifically: providing medical examination and treatment without a practice certificate and offering medical examination services without a license to operate as a medical examiner (First-Instance Criminal Judgment, 2023).

In short, the patient's right to bodily integrity, life, and health is a constitutional right of the highest order, clearly reflected in Articles 20 and 38 of the 2013 Constitution, providing a solid legal foundation for protecting patients. The legal system employs a multi-tiered approach, from the Constitution to the Civil Code to the Law on Medical Examination and Treatment, to protect patients' rights in both public and private settings. The legal liability framework is generally adequate, encompassing administrative, civil, and professional disciplinary liability for infringements of patients' health.

However, the Regulations on patient safety in the Law on Medical Examination and Treatment 2023 are still broad and lack specific quantitative standards. It remains difficult to prove medical professionals' fault in civil cases, creating practical obstacles for patients seeking compensation. The mechanisms for protecting patients' bodies and health are not closely connected to the accountability requirements of medical examination and treatment facilities.

There is no consistent regulation of mandatory national patient safety standards.

Lack of a no-fault compensation system for medical risks in specific cases.

There is no independent agency dedicated to safeguarding patients' rights and safety. The existing compensation system for damages caused by medical errors still follows the general rules of the Civil Code.

4. DISCUSSION

The risks of error and harm in the artificial intelligence (AI) era pose direct challenges to patient safety and well-being, requiring careful technical and ethical consideration (Wafaa et al., 2026). Based on the above research results, it is clear that although Vietnamese law is relatively well developed in terms of institutional mechanisms, its practical application remains limited because the regulations are overly general and lack specific guidance. In certain areas of traditional medical practice, the lack of specific guidance is sometimes compensated for by physicians' customary medical practices and established clinical routines. However, in the context of artificial intelligence, these inherent barriers are further intensified, alongside the emergence of new challenges. Legally, these risks challenge the traditional legal system. Below are specific analyses of the technological risks that create legal challenges within Vietnam's legal framework, organized into three areas: (i) Legal challenges to patients' rights regarding full-body integrity, health, and life. (ii) Legal challenges to equal access to healthcare. (iii) Legal challenges to informed consent.

4.1. Legal Challenges to Patients' Rights in the Age of Artificial Intelligence

In the AI era, the healthcare sector faces risks of errors and violations of patients' rights, including the possibility that AI algorithms, especially black-box models, may make mistakes in prediction, diagnosis, or decision-making (Wafaa et al., 2026). Specifically, AI algorithms are prone to errors in their predictions, forecasts, or recommendations (decisions) (Corfmat et al., 2025). The fundamental principle in developing AI models is that mistakes can occur due to the complexity of the underlying theory (Corfmat et al., 2025). Furthermore, the black-box nature of deep learning algorithms makes it challenging for both medical professionals and patients to understand how and why AI produces a particular outcome

(Corfmat et al., 2025). Additionally, the inherent complexity of algorithms, such as neural networks, complicates explaining the reasoning behind AI's recommendations (Nithesh et al., 2022). Meanwhile, patients' rights are traditionally rooted in a legal relationship of obligations, grounded in moral considerations, and limited to medical examinations and treatments provided by healthcare facilities and practitioners. However, in the context of AI, if patients' rights are confined to this relationship, they become less relevant. It is essential to broaden the scope of relationships and responsibilities of other stakeholders concerning patients' rights (Rabiega, 2012). Specifically, causes of errors include interference with clinical input data, discrepancies between training data and real-world data (Data Shift), or unforeseen variations in clinical environments (Shahriar et al., 2022). One such factor is that AI performance can be significantly impacted by noise and foreign objects (artifacts) in clinical input data (Nithesh et al., 2022; STOA, 2022). For example, minor, often imperceptible, alterations to input data (e.g., adding toxic pixels to medical images) can disrupt neural networks and lead to misdiagnoses, such as false cancer detections (Pouyan, 2020). Therefore, responsibilities should extend beyond medical practitioners and facilities to include developers and data providers (Ben et al., 2025). Additionally, errors can arise from data shifts between the data used to train AI and the data encountered in clinical settings. Models trained on data from one group or organization may not perform accurately when applied to another group with different demographics or characteristics (Nithesh et al., 2022). Lastly, AI algorithms may produce incorrect results due to unforeseen changes in the environment or context in which they are used. For instance, an AI system trained to identify lesions on chest X-rays might mistakenly classify foreign objects, like wedding rings or ECG connectors, as serious medical conditions (STOA, 2022). Therefore, it is important to establish a network of stakeholders involved in the development, deployment, and use of AI-powered medical tools to foster awareness of responsibilities across traditional ethical and legal boundaries (STOA, 2022).

In the AI context, the medical consequences of these mistakes can include failing to diagnose life-threatening conditions, misdiagnosing and leading to inappropriate treatment, and prioritizing incorrect interventions in emergency situations. Specifically: (i) The medical consequences of algorithmic errors include missed diagnoses of life-threatening conditions (STOA, 2022). (ii) Errors may result in misdiagnosis or inappropriate treatment recommendations (STOA, 2022). Errors can also lead to incorrect scheduling or prioritization of interventions (British Medical Association, 2024). (iii) Generally, these medical errors may jeopardize patient safety and result in death or injury (STOA, 2022).

Currently, all clinical decisions are made by the medical practitioner. However, when a medical examination and treatment facility uses medical devices and equipment that support AI technology, it remains unclear whether the doctor has the right to refuse to use these devices and whether the risk and responsibility ultimately fall on the doctor (Pouyan, 2020). It is also unclear whether doctors are liable for refusing to use AI-powered medical devices if AI's warnings are truly effective in identifying diseases and treatments. Not using AI can lead to common mistakes among doctors and medical facilities, whereas using AI helps prevent them (Santoni & Mecacci, 2021).

Meanwhile, improper use of the system, such as due to a lack of training or overtrust in technology (automation bias) by medical professionals, can also lead to errors and patient harm: (i) Misuse can happen when medical professionals have limited knowledge of AI and are not properly trained (STOA, 2022). (ii) Users may increase automation bias, which is a tendency to overtrust automated decisions (British Medical Association, 2024). (iii) When health professionals rely too much on assistive tools like AI, they may develop cognitive complacency, leading them to ignore necessary skills or accept the system's results without questioning its limitations (Nithesh et al., 2022). (iv) This lack of understanding and overtrust can cause inaccurate medical assessments and clinical decisions, potentially harming patients (British Medical Association). (v) Conversely, users might ignore the system's results (e.g., due to misreading or perceiving them as too different from their own judgment) (Corfmat., et al).

These contradictions in the traditional legal framework clearly highlight the need for a more integrated approach and a thorough review of patients' rights in relation to the parties' obligations (Pham, 2025).

On June 3, 2024, Deputy Minister of Health Do Xuan Tuyen was present at the Ministry of Health and signed the document consolidating No.04/VBHN-BYT (Ministry of Health, 2024). It includes the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, which regulates the management of medical devices; the Government's Decree No. 07/2023/ND-CP dated March 3, 2023,

which amends and supplement several articles of Decree No. 98/2021/ND-CP; and the Government's Decree No. 96/2023/ND-CP dated December 30, 2023, which details certain articles of the Law on Medical Examination and Treatment. It clearly states that medical devices must ensure quality, safety, and effective use; provide complete, accurate, and timely information about technical characteristics, uses, and potential risk factors for users; and ensure traceability BYT (Ministry of Health, 2024).

The management of medical devices must be based on risk classification and the relevant national standards and regulations issued and recognized by appropriate government agencies, or on standards announced and used by organizations and individuals in accordance with the law. However, there is no specific regulatory guidance for devices that support AI technology (Nguyen, 2025a).

According to Article 4 of No.04/VBHN-BYT, medical devices are divided into four categories based on the potential risks related to their engineering design and manufacturing (Ministry of Health, 2024).

Category A medical devices are considered low-risk devices.

Category B medical devices pose a low-to-moderate risk level.

Class C medical devices carry a medium level of risk.

Class D medical devices are considered high-risk devices.

The classification of medical devices should follow the risk-level classification rules.

However, the regulations on classification, issuance of circulation numbers, and declaration of eligibility for trading under this Decree do not apply to software used for medical devices (Article 3, Clause 8, Point a of the Consolidated Document of Decree 98/2021/ND-CP (amended, supplement)).

Meanwhile, AI is a component of medical equipment (software) that supports diagnosis and treatment (Krishnan, 2021). For example, AI integrated into diagnostic imaging machines adjusts ventilator settings in real time. However, because AI medical devices are considered similar to device control software, they do not receive a separate AI registration number; AI is assessed as part of the overall device. If Article 3, Clause 8 is applied specifically, it does not require classification, the issuance of registration numbers, or the declaration of eligibility for equipment procurement, indicating that the current management trend under Vietnamese law can exempt software in medical devices from administrative procedures. However, future trends suggest a need for more specialized management under technical or AI-related regulations in healthcare (Nguyen, 2025a).

4.2. Legal challenges to fair access to healthcare

AI risks worsening existing inequalities and unfairly discriminating against disadvantaged groups (Corfmat et al., 2025).

AI algorithms learn from data, and if that data reflects or lacks representation of social biases, the model replicates and amplifies those biases, leading to discrimination. Sources of bias include: (i) Societal and Historical Bias (Fazakarley et al., 2024): Training data often contain social biases related to race, gender, age, and socioeconomic status. For example, an algorithm that predicts healthcare needs may be racially biased because it uses medical costs (which are lower for Black patients due to difficulties in accessing services) as a measure of health needs, causing their needs to be underestimated (Pouyan, 2020). (ii) Unrepresentative Data (Mykhailo et al., 2023): Training datasets may be too small, incomplete, or unrepresentative of the diversity of the target population (e.g., lack of data from minorities, women, or dark-skinned individuals) (Corfmat et al., 2025). This results in AI models that are less accurate for underrepresented groups, leading to misdiagnoses or treatment delays. For example, dermatological diagnostic tools trained primarily on data from white skin may be less accurate for darker skin tones (Corfmat et al., 2025). (iii) Contextual Bias: Data are often collected from countries or health facilities with well-developed economies, making models ineffective when used in low-income or rural areas where clinical conditions differ significantly (Hannane, 2020).

Consequences of algorithmic bias (Shahriar, 2022): (i) Algorithmic bias causes discrimination in healthcare, impacting resource allocation and quality of care (Kumar et al., 2023). (ii) Using AI systems that ignore patient diversity can worsen existing health disparities and hurt marginalized groups.

Access barriers and inequality: AI, a high-cost technology with complex operational features, can widen the gap between those with access and those without, affecting not only patients but also medical facilities (STOA, 2022).

Digital divide: (i) The deployment of AI services risks widening the digital divide, making it harder for older adults, rural residents, or those with low digital literacy to access and use these tools (Goktas & Grzybowski, 2025). (ii) AI can enhance healthcare access in areas with doctor shortages, but this requires strong digital infrastructure (internet,

equipment), which is often lacking in developing countries or rural regions (Amjad et al., 2023).

Affordability and resource allocation: AI has the potential to lower healthcare costs by automating administrative tasks and enhancing diagnostic efficiency (Amjad et al., 2023). However, the initial expenses of developing, deploying, and maintaining AI systems are very high (Amjad et al., 2023). Consequently, we recognize that equal access to healthcare may encounter new challenges as concerns about growing inequality arise in the AI era. Particularly amid the trend of scientific and technological progress, the digital transformation of the national health system—encompassing health management agencies and insurance organizations that use artificial intelligence—and the digital transformation of medical resource allocation, including priority setting, will influence the insurance framework. Therefore, health systems at all levels, from central to local, must clearly define the obligation to strengthen training for human resources across all tiers, establish new regulations on public procurement (including software and technology procurement) to support the development of the health system, and mitigate the impact of increased inequality in healthcare access. This obligation directs state agencies to allocate budgets for health system management, including public procurement and the development of technological infrastructure.

Currently, Vietnam has not officially implemented or regulated the use of artificial intelligence (AI) to identify or develop groups eligible for special health budgets. The process for identifying these groups mainly relies on:

1. Traditional socio-legal practices, not AI decision-making models, determine priority groups and special health budgets. The current basis for these decisions includes: the Law on Health Insurance; the Law on the State Budget; the Law on Medical Examination and Treatment 2023; and decrees, resolutions, and decisions from the Government and the Prime Minister. Examples include: poor and near-poor groups; children under 6 years old; the elderly; people with meritorious services to the revolution; ethnic minorities in extremely difficult areas; and individuals suffering from serious and rare diseases (within some program scopes).
2. Other criteria include: "Legal identification" criteria such as personal identity, household registration, and residence area; "Socio-economic" criteria such as living standards and disadvantaged areas; and the "Epidemiology" criterion, such as infectious diseases and diseases prioritized for prevention.

The first challenge is that there are no criteria based on AI algorithms or machine learning models. There is also no legal framework that allows AI to make policy decisions—no law or decree authorizes AI to participate directly in the budget allocation process. However, AI can support analysis and forecasting, such as identifying high-risk areas for disease and evaluating the budget impact of health policies. While AI does not make decisions about health budget allocation, AI "technical assistance" can influence decision-making—and is likely to have a significant impact. This level of influence doesn't mean AI becomes the decisive factor; legally, responsibility remains with state agencies. Still, AI can influence aspects like: (i) shaping how problems are viewed; (ii) prioritizing options; and (iii) highlighting or blurring certain groups.

Specifically, AI influences policy by shaping input data, as the budget is allocated based on disease data, service use frequency, and medical demand forecasts. When AI analyzes big data, identifies disease "hot spots," and estimates cost-effectiveness, what it "shows" becomes the basis for policy decisions. For example, if AI forecasts an increase in non-communicable diseases in urban areas, the responsible authority may choose to prioritize the budget for this group; if AI detects low service utilization rates in remote areas, the authority may decide to reduce the allocation without a proper policy review in the current context.

Next, AI influences policy through the framing effect. Using AI systems, it becomes possible to standardize the problem by indexing, providing rankings, and risk models. This may lead policymakers to prioritize what is quantifiable over what cannot be easily measured. All these impacts risk undermining social justice factors (Faraj et al., 2025).

Within Vietnam's legal framework, budget decisions must always identify the responsible parties, who can be examined, inspected, and audited. Regardless of how AI influences decisions, the individual authorized to sign the decision remains fully accountable. However, the current legal gap includes the lack of an obligation to disclose the use of AI in policy analysis; the absence of mechanisms to evaluate algorithmic impact; and the absence of a provision for the right to criticize AI-generated recommendations (Nguyen, 2025b). This means that, in practice, the influence of AI exists but

has not yet been formally recognized in the law (Nguyen, 2025b). Due to the legal structure, AI is not involved in the decision-making process for medical budget allocation. In essence, AI can significantly influence decisions by providing data, framing the problem, and establishing a priority framework.

4.3. Legal challenges to informed consent

The rapid growth of artificial intelligence (AI) has ushered in a new era for the healthcare industry, promising advances in diagnosis, treatment, and management (Astromskė et al., 2021). However, the use of AI in healthcare also introduces numerous ethical and legal issues, especially regarding informed consent (Gerke et al., 2020). Informed consent is a core principle in medicine that ensures patients have the autonomy to make decisions about their health care once they are fully informed about the treatment options, risks, and benefits (Andreotta et al., 2022). As AI becomes more integrated into healthcare, ensuring patient-informed consent has become more complicated (Astromskė et al., 2021). Patients often do not know if AI is involved in their diagnosis and treatment (Park, 2024). This raises an important question: Should doctors be required to disclose the use of AI tools in clinical decisions, and what information should they provide to help patients make voluntary, informed choices? (Park, 2024).

The use of AI in healthcare provides many benefits but also introduces risks that exacerbate the challenges of informed consent.

Increased risk of issues with informed consent when using artificial intelligence in healthcare

First: Risks Related to Transparency and Explainability

For AI systems, especially deep learning models often called "black boxes" (Andreotta et al., 2022), it is difficult even for developers to fully and clearly explain how AI makes decisions (Astromskė et al., 2021). This makes it difficult for doctors to provide patients with detailed, accurate information about AI-generated treatment recommendations (Andreotta et al., 2022; Wafaa et al., 2026). As a result, patients may feel confused and lose trust if they don't understand why the AI reaches such diagnostic conclusions or makes such recommendations (Astromskė et al., 2021).

Second: Bias risk and fairness

AI training data may include biases from historical or social influences, which can result in unfair diagnostic or treatment outcomes for certain patient groups (e.g., due to racism, gender, or age) (Gerke et al., 2020). Patients should be informed about the potential for bias in AI systems and be empowered to make their own final healthcare decisions (Astromskė et al., 2021).

Third: Privacy and Data Security

Using AI in healthcare involves collecting and analyzing large amounts of personal medical data, which raises the risk of data privacy and security breaches (Gerke et al., 2020).

Patients should be informed about how their data will be used to train and operate the AI, who will have access to it, and what security measures are in place to prevent misuse or unauthorized access (Astromskė et al., 2021).

Fourth: Patient Autonomy

Over-reliance on AI systems can diminish the involvement of doctors and patients in clinical decision-making, compromising patient autonomy (Park, 2024). Consequently, patients might feel compelled to follow AI recommendations even if they do not fully agree with or understand the reasons (Astromskė et al., 2021).

Fifth: Accountability

In AI, who is responsible for providing patients with information to help them make their final decision about whether to accept AI-powered therapy? The entire AI life cycle is unclear, so if AI causes errors in diagnosis or treatment, it becomes impossible to determine who is legally responsible (Astromskė et al., 2021).

Without identifying errors in how information is provided, it is impossible to determine whether medical practitioners, AI developers, and medical facilities are responsible (Astromskė et al., 2021). Meanwhile, doctors and patients are interested in the obligation to provide information as a basis for determining responsibility in medical incidents involving the use of AI in examinations and treatment (Astromskė et al., 2021).

Last: Legal standards are unclear.

Currently, there is no specific legal standard for informed consent in the use of AI in healthcare (Park, 2024). This makes it difficult for doctors and nurses to determine which information to provide to patients to meet legal requirements. The lack of legal clarity also creates liability risks for medical practitioners and medical facilities (Park, 2024).

Obligation to disclose the use of artificial intelligence in diagnosis and treatment

Currently, the Law on Medical Examination and Treatment 2023 does not specify regulations regarding the obligation to inform patients. In Vietnamese law, informed consent ends at the standard "consent" regulation, which also covers invasive medical procedures.

Therefore, Vietnamese law must undertake two tasks: first, establish regulations on informed consent to support and uphold the patient's right to self-determination; second, regulate informed consent in the age of artificial intelligence. This presents both opportunities and challenges. Accordingly, in addition to exploring the fundamental theory of informed consent from moral philosophy to legal justification, Vietnam needs to adapt to the social context - the era of artificial intelligence (Nguyen, 2026). There are differing opinions on whether healthcare professionals should disclose the use of AI in patient care (Wałdoch, 2024).

From the perspective that medical practitioners must disclose information about the use of AI in treatment, based on the following arguments:

1. Respect for autonomy: Patients have the right to be informed of all factors that can influence their treatment decisions, including the use of AI (Astromskė et al., 2021).

2. Building trust: Sharing information about AI helps foster trust between doctors and patients (Astromskė et al., 2021).

3. Addressing concerns: By providing clear, accurate information, doctors can alleviate concerns and help patients feel more at ease and confident using this technology (Wałdoch, 2024).

4. Ensuring transparency: Sharing information about AI improves openness in the healthcare system (Gerke et al., 2020).

The opposition to disclosing information stresses that, in some cases, a medical practitioner might not be required to fulfill this obligation if:

1. Disclosing AI use can cause patient anxiety: Sharing excessive technical details about AI may confuse patients, particularly those unfamiliar with the technology (Wałdoch, 2024).
2. If AI only has a minor supporting role in decision-making, disclosing information may be unnecessary and time-consuming for doctors and patients (Park, 2024).
3. Comparison with other medical tools: AI can be viewed as an aid, similar to tests or X-rays. Doctors do not need to explain in detail how these tools operate, as long as they provide clear information about their results and implications (Wałdoch, 2024).
4. Risk of decreased trust: Some individuals worry that revealing information about AI might reduce patients' trust in doctors and the healthcare system if patients lack accurate knowledge of AI (Park, 2024).

Scope of information to be given to patients

When deciding whether to disclose information about the use of AI, what details should medical practitioners provide to ensure the principle of patient-informed consent (Park, 2024)?

Purpose and role of AI: Medical practitioners must clearly explain the purpose of using AI in the patient's specific case (e.g., assisting with diagnosis or treatment selection) and the role of AI in decision-making (e.g., providing information or making recommendations) (Astromskė et al., 2021).

How AI works (at the right level): Offers a simple overview of how AI functions, focusing on input data, processing, and outputs (Wałdoch, 2024). Avoid using overly technical terms that can confuse and hinder understanding (Astromskė et al., 2021).

1. Accuracy and limitations of AI: Medical practitioners should always recognize that AI is not perfect and can make mistakes (Park, 2024). The AI system's proven accuracy and limitations should be clearly communicated (Park, 2024).
2. Risks and benefits: Discuss with the patient the potential risks of using AI (such as algorithmic errors and data biases) and the benefits (such as quicker diagnosis and more effective treatment) (Park, 2024).
3. Patients' right to choose: Emphasizing patients' right to refuse AI use and to select alternative treatments (Andreotta et al., 2023).
4. Data Security: Describe how the patient's data will be used, shared, processed, and protected (Gerke et al., 2020).
5. Right to Interpretation: States that the patient has the right to ask for more details about how the AI makes suggestions and the reasoning behind those suggestions (Astromskė et al., 2021).
6. Contact information: Provide the contact details for the person responsible for the AI system so the patient can ask questions or file complaints if needed (Astromskė et al., 2021).

5. CONCLUSION

This article affirms that patients' rights to bodily integrity, life, and health are strongly embedded in Vietnam's constitutional and statutory law, and that recent legislative developments reflect a progressive shift toward preventive and safety-oriented healthcare governance. By codifying patient safety and risk management, the Law on Medical Examination and Treatment 2023 marks an important step toward strengthening patients' legal protection.

However, the emergence of artificial intelligence

fundamentally challenges traditional legal approaches to patients' rights. AI reshapes the structure of medical decision-making and broadens the range of relevant actors beyond physicians and healthcare institutions to include software developers, data providers, and technology vendors. Despite this change, Vietnamese law does not yet regulate AI as an autonomous object of legal control in healthcare, nor does it provide specific standards for accountability, transparency, or risk allocation in AI-assisted medical practices.

Most critically, the absence of clear legal requirements for informed consent regarding AI risks weakens patient autonomy. Without explicit obligations to inform patients about the role, limitations, and risks of AI technologies, they may not be able to make truly informed choices about their medical care. Additionally, unchecked AI deployment can worsen existing healthcare inequalities, especially for vulnerable groups impacted by data bias, digital exclusion, and financial barriers.

Given these challenges, the article concludes that urgent legal reform is necessary. Vietnamese law should establish specific standards for patient safety, algorithmic transparency, accountability, and AI-specific informed consent, as well as independent oversight mechanisms. Only with such reforms can the use of AI in healthcare align with the core goal of protecting patients' rights and dignity in the digital age.

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