JOURNAL OF CULTURAL ANALYSIS AND SOCIAL CHANGE

Journal of Cultural Analysis and Social Change,
2025, 10(2), 1952-1962
ISSN: 2589-1316

Application of Artificial Intelligence in the Healthcare Sector and Legal Challenges: A Study in Vietnam

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Citation: Cham, N. T. P. (2025). Application of Artificial Intelligence in the Healthcare Sector and Legal Challenges: A Study in Vietnam, *Journal of Cultural Analysis and Social Change*, 10(2), 1952-1962. https://doi.org/10. 10.64753/jcasc.v10i2.1894

Published: November 15, 2025

ABSTRACT

In Vietnam, recent discussions in official and academic forums have highlighted the positive role of artificial intelligence (AI) in the healthcare sector. Like other countries, Vietnam expects that through the fourth industrial revolution, particularly AI, its current healthcare system will undergo significant improvements. In policy and practical application, Vietnam has demonstrated that AI is indispensable in developing a healthcare system that faces numerous challenges in human resources. In light of recent global developments, it is clear that AI not only brings significant benefits, such as improving efficiency and reducing costs, but it is also predicted to pose numerous risks to society in both ethical and legal aspects. To minimize and eliminate hazards, the current legal framework can respond to the new context. To address these questions, this paper examines the current state of AI applications in Vietnam and reviews the existing legal frameworks in the country. The research results indicate that Vietnam's current legal frameworks are insufficient to ensure the rights and interests of patients against potential risks posed by AI. Finally, the paper proposes that in addition to soft laws, such as the principle of responsible AI for general subjects, hard laws are needed to achieve the goals of AI in the healthcare sector. This includes regimes on health data to ensure privacy, prevent bias and injustice, and regulations on approval processes for AI medical devices to ensure patient safety.

Keywords: Artificial Intelligence (AI); AI Risks; Healthcare Sector; Ethical Challenges; Vietnam Legal

INTRODUCTION

Vietnam has started developing and using AI in diagnostics and clinical treatment(Đào Việt Hằng et al., 2024; Nguyen Quang Duy, 2024; Nguyễn Thị Thu Thảo et al., 2025; Nguyễn Văn Diễn & Nguyễn Thùy Trang, 2025; Phạm Diệu Linh et al., 2025; H. T. Pham et al., 2024a; Trần Đức Hải et al., 2023). Along with the global trend of implementing generative AI in healthcare, such as enhancing physicians' work efficiency (Clinical Administrative Support, Clinical Decision Support) and summarizing and explaining highly specialized medical documents to patients, Vietnam is also actively developing more advanced services. These include AI that generates medical records while understanding the context of patient-doctor conversations, as well as conversational AI that recommends optimal health-promoting actions for each user through dialogue (Patient Engagement) (Reddy, 2024).

However, by studying the historical development of AI in medicine, scholars have found that "as AI clinical AI systems mature, there will be an inevitable increase in their clinical use and development, which will lead to new social, economic, and legal issues" (Nguyen Quang Duy, 2024; Than & Liu, 2024). For example, a model trained on generic data may not handle academic or technical terms correctly, and the output generated may contain uncertain information (Williamson & Prybutok, 2024). Furthermore, if the referenced data includes

unreliable information, it could even endanger the health or lives of users (Singla et al., 2024). There is also a risk that personal information collected may be used for unintended purposes or leaked in the process (Esmaeilzadeh, 2020) .

Any country's healthcare system must be human-centered. Ethical and legal issues are always two sides of the goal in healthcare (Bataineh et al., 2024). The emergence of new technologies, such as AI, will impact society and individuals in ways very different from traditional methods (Ayesha et al., 2023). Identifying the issues and needs of each country in development orientation plays a vital role in promoting development (Than & Liu, 2024).

However, as a developing country, Vietnam focuses more on AI's benefits to the healthcare system. Thus, more in-depth research is needed on the impacts and challenges AI will bring to Vietnamese society (H. T. Pham et al., 2024b; Than & Liu, 2024; Vuong et al., 2019). This research is motivated by the scarcity of studies on this topic in Vietnam. It aims to provide an objective foundation for a persuasive recommendation to develop a legal framework for AI in healthcare in Vietnam to fill the current gap. The research issues can be summarized as follows:

(a) AI development policies in the healthcare sector in Vietnam;
(b) AI applications in clinical practice in Vietnam;
(c) Identifying ethical and legal challenges from social realities and the gap in legal regulations.

The outcome is expected to provide an objective foundation for several persuasive recommendations to develop a legal framework for AI in Vietnam to fill the current gap and forward a sustainable healthcare system in Vietnam.

MATERIALS AND METHOD

Materials

AI Aplication in Healthcare sector in Vietnam

Some studies have analyzed the current situation of AI application in the health sector in Vietnam, specifically below:

First: Lung X-ray: At Cho Ray Hospital, the AI system (Model Lunit CXR-v3, using CNN convolutional neuron network combined with ResNet architecture) has been deployed since February 2022 to support the analysis of straight chest X-ray results, processing 24,120 cases.(Trần Đức Hải et al., 2023) This system brings a breakthrough solution for quick and easy disease screening, as in Thanh An island commune, Can Gio, AI can accurately analyze and identify 95 types of lesions in just 10 seconds after a chest X-ray, a possibility that previously only specialists could do.(Nguyễn Văn Diễn & Nguyễn Thùy Trang, 2025)

Second: Chest CT for the diagnosis of lung cancer: An AI application (CaraNet model) developed at Bach Mai Hospital in collaboration with Hanoi National University has been tested.(Nguyễn Thị Thu Thảo et al., 2025) AI is capable of diagnosing solitary lung tumors, including small ones (from 12mm), and typical benign lesions such as frosted glass, bud-like lesions on branches.(Nguyễn Thị Thu Thảo et al., 2025)

AI can assist in reducing load and speeding up photo reading by automatically marking suspicious locations. However, AI is limited in assessing calcification, cavitation, and is easily confused with inflammatory lesions, especially rare diseases such as inflammatory or metastatic lung cancer, or extensive coagulation lesions.(Nguyễn Thị Thu Thảo et al., 2025).

Third: Diabetic retinopathy screening: At Hospital E, the application of AI (Cybersight AI platform of Orbis organization) in diabetes screening has been surveyed from July 2022 to February 2024.(Phạm Diệu Linh et al., 2025)

The lack of medical personnel specializing in retinopathy and the large number of diabetic people who need to be screened is a big challenge, and AI helps reduce this burden.(Phạm Diệu Linh et al., 2025) AI does not need an ophthalmologist to perform it, helping to screen a large number of patients in a short time (less than 1 minute for each case analyzed).(Phạm Diệu Linh et al., 2025) The limitations of AI include the failure to evaluate cases of transparent environmental opacity (e.g., vitreous opacity) and large initial investment costs.(Phạm Diệu Linh et al., 2025)

Fourth: Gastrointestinal endoscopy:

AI has recently been deployed in Vietnam to support gastrointestinal endoscopy, in order to overcome the dependence on doctors' skills and minimize missed lesions.(Đào Việt Hằng et al., 2024) Deep learning AI algorithms are researched to automatically detect anatomical landmarks, assess quality, and detect common lesions.(Đào Việt Hằng et al., 2024)

Research on AI in Healthcare in Vietnam

The U.S. Food and Drug Administration (FDA) has officially approved the VinDr application for market release in the United States. VinDr can automatically classify mammography images and detect suspected breast cancer cases with an accuracy of 96.5% for Vietnamese data and 95.8% for American data (Nguyen Quy Ha, 2024).

VinDr is an AI-based system, developed in Vietnam, to analyze medical images such as chest X-rays, mammography, and urinary tract ultrasound/CT scans to detect lung diseases and breast, testicular, and prostate cancers. This system has been thoroughly evaluated by reputable tertiary care centers in Vietnam.(Doan Thu et al., 2023)

The VinDr system has been thoroughly evaluated by reputable tertiary care centers in Vietnam, including the 108th Military Central Hospital, Hanoi Medical University and Vinmec Health System.(Doan Thu et al., 2023)

A related dataset, VinDr-Mammo, is a large-scale Vietnamese school-wide digital mammography dataset, including 5,000 four-dimensional mammography with mammography assessment and lesion-level detailed annotations. This dataset was retrospectively collected from the 108th Military Central Hospital and Hanoi Medical University Hospital. The mammography cases are read independently by two radiologists and any inconsistencies are resolved by arbitration with the participation of a third radiologist. Radiologists involved in the data annotation process are certified in medical practice, require up to 8 years of training, and have an average of 19 years of clinical experience in mammography.(Nguyen et al., 2023)

Identifying Risks in the Healthcare Sector

AI provides numerous benefits, and advocates for developing and implementing AI-based medical applications in developing countries have shown the current and future advantages that AI technology can offer to healthcare (Alami et al., 2020).These benefits primarily focus on (1) improving the efficiency of the healthcare system and (2) reducing costs (Guo & Li, 2018).

Implementing AI research and applications poses numerous social and ethical risks in a global context, and the application of AI in the healthcare sector presents several challenges (khan et al., 2023). AI-based healthcare applications face numerous potential risks and limitations, particularly in developing countries. Numerous studies have demonstrated that AI poses specific ethical risks to developing countries. For example, these applications are still in their early stages, with few appropriate evaluations and inadequate infrastructure (Dang et al., 2024). AI developed in developed countries is often used without being thoroughly tested for its social suitability (Guo & Li, 2018). These reasons exacerbate the inherent potential risks of AI in the medical field even further in developing countries, such as Vietnam (Vuong et al., 2019).

After AI has been used for a significant amount of time, the practical risks that arise will need to be monitored. Currently, Vietnam has no publications addressing signs of AI encroachment in the medical field. Whether or not serious ethical violations have occurred, it is essential to highlight potential risks and evaluate if existing policies and laws can manage these emerging issues. From a global standpoint, deploying AI in healthcare will inevitably involve ethical risks.

The first risk may come from data concerns

Data Quality, Availability, and bias, discrimination risks: Developing AI health applications requires large amounts of high-quality data, which can be difficult to collect, especially in developing countries. This poses a high risk of creating social biases and injustices when applying AI in healthcare (e.g., gender, ethnicity, age). A significant concern when applying AI in healthcare, particularly in Vietnam, is that most AI-based health applications are trained using data from high-income countries (The Lancet Public Health, 2019). This can inadvertently cause biases or discrimination against populations in developing countries. Although algorithms are often considered objective, they are inherently subjective and are created based on the values, beliefs, and norms of the developers and data collectors (Faraj et al., 2018).

Data Collection Concerns and Privacy and Security: The collection and use of personal data by AI and analytical algorithms raises serious issues, including privacy violations, fraud, a lack of transparency, algorithm abuse, information leakage, and identity theft (Sivarajah et al., 2017). In Vietnam, data collection presents numerous challenges related to privacy, particularly with regard to medical data (Vuong et al., 2019). This sensitive personal data directly impacts social relationships, including those with coworkers, family, and friends. Therefore, data collection in this group must have specific standards to ensure patient privacy.

The second concern comes from AI's transparency (Accuracy and Reliability)

The patient's right to self-determination when using AI applications in Vietnam remains subject to numerous assumptions. Respecting patient autonomy: From ethical to legal aspects, patient autonomy fosters trust between patients and healthcare facilities/doctors, one of the critical factors in developing a sustainable healthcare system (Kumar et al., n.d.). Do patients have information about the reality that they are receiving a diagnosis, treatment plan, or prescription with the support of AI?

AI can make erroneous judgments and still make undetectable errors or have negative impacts that could lead to catastrophic consequences, harming patients' health and lives (Nuffield Council on Bioethics, 2018). Therefore, patients can decide whether to accept treatment from AI-assisted physicians. Patients must be informed and give consent when using these applications.

The third concern comes from accountability

When a patient encounters harm, whom does the patient ask for an explanation? Who is responsible for explaining to the patient how AI is applied in treatment and support?

The difficulty in validating AI systems is due to the complexity of the AI algorithms and lack of understanding of how an algorithm has reached a conclusion on determining a particular diagnosis or predicting the suitable treatment for the patient (Saraswat et al., 2022). In the healthcare sector, a patient's record data and indicators span across time and are interconnected in multiple ways, forming a non-linear relationship (Saraswat et al., 2022). Hence, the predicted results by AI models are not easily interpretable by the end users, including physicians and other healthcare professionals (Palaniappan, Lin, & Vogel, 2024). Enhancing the interpretability and explainability of AI models is crucial for promoting the acceptance and trust of AI in healthcare services among healthcare providers (Palaniappan, Lin, Vogel, et al., 2024).

Finally, the legal liability mechanism

Medical Malpractice is always a complicated issue (Eslamitabar et al., 2023). Since AI intervention requires the participation of multiple parties, including the AI developer, data provider, service/product provider, and user, civil liability related to these traditionally complicated relationships becomes even more complex (Anishchenko et al., 2023). Developing countries face more complex problems; most still rely on imported AI medical devices (khan et al., 2023).

METHOD

The present research study includes five steps: Investigate practical framework; Set the research questions; Analyze legal frameworks; Results & Discussion and Implications; and Future Directions.

The first step involves reviewing and investigating related works to identify the research issue. In the second step, the literature is thoroughly analyzed to demonstrate the main AI applications and techniques employed in the healthcare sector in Vietnam and their challenges. The primary goal of this study is to illustrate how AI is integrated and utilized in the Vietnamese healthcare sector. Step 3 is dedicated to examining legal frameworks addressing the risks and highlighting the legal gaps. A comprehensive observation method is prepared and distributed. Step 4 entails a detailed discussion of the results obtained from the analysis. Finally, step 5 assesses the significance of AI for the future of healthcare in Vietnam.

RESULT AND DISCUSSION

This article analyzes the current Vietnamese legal framework regarding solutions to numerous social and ethical risks from a global philosophical perspective that is patient-centric within the healthcare system. Discussing the rights of patients, Vietnamese law focuses on two fundamental rights: (1) body, life, and health; (2) health information and other personal information (personal data - privacy rights).

The Vietnamese Legal System

Vietnam's legal sources concerning rights to the body, life, and health.

First, the Constitution of the Socialist Republic of Vietnam 2013 (hereinafter "2013 Constitution") recognizes the rights to body, life, and health in Article 20(1). Next, Article 33 of The Civil Code of The Socialist Republic of Vietnam 2015 (hereinafter "2015 Civil Code") affirms: (1) Each individual has the right to life, the inviolable right to life and body, and the right to health protection by law. No one shall be killed illegally. (2) When any person has a life-threatening accident or illness, a person who discovers such a situation must take such a person or suitable entities to the nearest health facility; the health facility must provide medical examination and treatment according to the law on medical examination and treatment. (3) A person's consent is required for anesthesia, surgery, amputation, transplant of his/her tissues or bodily organs, the application of

new medical cures to that person, medical, pharmacy, scientific testing, or any method of testing on a human body.

From the perspective of specialized law, Vietnam recognized 06 rights of patients when examining and treating diseases stipulated in the Law on Medical Examination, Treatment of the Socialist Republic of Vietnam 2023 (hereinafter "Law on Medical Examination, Treatment to ensure the direct benefits of patients regarding life and health. According to the content of Chapter 2 of the Law on Medical Examination and Treatment 2023, which stipulates the rights and obligations of patients (or patients), patients will have the following rights: Right to medical examination and treatment (Art. 9); Right to respect for honor, protection of health and respect for privacy in medical examination and treatment (Art.10); Right to choose in medical examination and treatment (Art.11); Right to be provided with information about medical records and medical examination and treatment costs (Art.12); Right to refuse medical examination and treatment and leave the medical examination and treatment facility (Art.13); Right to make recommendations and compensation (Art.14).

Legal Framework for the Protection of Health Data Privacy

The 2013 Constitution states: "Everyone has the right to inviolability of private life, personal secrets, and family secrets; has the right to protect their honor and reputation. Information about private life, personal secrets, and family secrets is protected by law" (Art . 21).

The 2015 Civil Code also affirms in Art. 38(1): "Private life, personal secrets, and family secrets are inviolable and protected by law."

Moreover, the 2023 Law on Medical Examination and Treatment includes specific regulations within the healthcare sector. Section 1, Chapter 2 of this law outlines "Patient Rights," emphasizing in Articles 10(1) and (2) the rights of patients: "The right to respect for honor, protection of health, and respect for privacy in medical examination and treatment."

Several Limitations of Regulations

Related to Protecting Patients in the AI Implementation Context.

Vietnamese law is relatively comprehensive in protecting patients' rights to health and life. However, legal relationships in the medical field always involve ethical aspects. AI's impacts on ethics and traditional law pose many legal challenges (T. Pham, 2025).

The regulations recognized human rights and provided for enforcement in cases of violation, such as civil, administrative, and criminal sanctions.

However, regulations that serve as preventive measures against harmful acts, which are considered suitable for the healthcare sector to address emerging issues such as AI, are still lacking.

Firstly, medical devices play a crucial role in medical examination and treatment activities. The assessment of quality, compatibility, and safety is indispensable. The medical law of any country, including Vietnam, has regulations to regulate and control all activities related to medical devices (MDs). Nowadays, with the advent of AI, MDs have improved. However, the operating mechanism of MDs has undergone significant changes, so it is necessary to amend the corresponding law to ensure that AI medical equipment is used in a manner that meets the conditions required and ensures patient safety. To adapt to the AI era, some countries have taken action with their laws. Unlike other jurisdictions such as the United States , Japan , Singapore , China , etc., which have laws regulating MDs in the context of AI assisting doctors in medical examination and treatment activities, Vietnam has not yet developed any legal documents regulating AI-medical devices (AI-MDs). The Law on Pharmaceuticals 2016 and the Law on Medical Examination and Treatment are the primary legal documents regulating the licensing and management of medical devices. However, they do not specifically address medical devices using AI technology (AI-MD). AI-MD must follow the general licensing procedures for medical devices; however, there are no specific standards or regulations for AI–MD (Nguyen Quang Duy, 2024). Decree 98/2021/ has not been updated to include specific requirements and standards for AI-MD. This creates legal challenges in managing and supervising emerging AI-MD. This causes ethical and legal risks. In terms of ethics, this device is not transparent, and both doctors and patients feel skeptical when using a product without knowing whether the traditional device appraisal process applied to this emerging device is reasonable. In terms of law, there is a lack of control mechanisms to prevent risks from occurring.

Secondly, clinical trials are crucial to ensure the safety and efficacy of medical products before they are widely used. This process becomes more complex for AI-MD in healthcare due to AI's autonomous and continuously learning nature. According to current regulations in Vietnam, medical products, including devices and software, must undergo clinical trials before being licensed. However, these regulations mainly apply to traditional products; the latest regulation in the healthcare sector is the Government Decree on the Elaboration of the Law on Medical Examination and Treatment (December 30, 2023) , which has yet to regulate clinical

trials of AI-MD (Nguyen Quang Duy, 2024). Clinical trials with AI-MD have not been conducted based on risk classification, posing challenges in protecting patients' physical integrity, health, and lives.

Thirdly, from the theory of informed consent, the current lack of pre-testing legal regulations to ensure the safety of the disease poses ethical risks in the medical field (Ruth R. Faden & Tom L. Beauchamp, 1986). When medical facilities and doctors utilize AI-MDs without a corresponding and appropriate safety assessment mechanism, patients have the right to receive information and decide whether to accept AI-assisted diagnosis and treatment (Esmaeilzadeh, 2020). From this ethical perspective, it will also pose legal challenges regarding the doctor's obligation to provide information before diagnosis and treatment with the device's support (Ruth R. Faden & Tom L. Beauchamp, 1986). Vietnam's legal frameworks are largely ineffective in implementing these regulations and fail to establish an obligation for physicians to provide information to help patients obtain informed consent.

Lastly, AI in medicine will inevitably result in legal challenges regarding medical negligence attributed to complex decision-support systems. When malpractice cases involving AI-MDs arise, the legal system will need to provide clear guidance on who is liable (Yu et al., 2018). However, in Vietnam, many aspects of legal responsibilities when AI-MD infringes on patients' rights and legitimate interests remain unclear(H. T. Pham et al., 2024b). This includes the relationships between healthcare facilities and medical practitioners, healthcare facilities and AI product providers, and AI product providers and AI developers within the healthcare sector.

The Limitations of Legal Framework for the Security of Health Data Privacy

Healthcare facilities need mechanisms to build trust with patients so they can proactively share all personal information, including sensitive health information. The examination, diagnosis, treatment, and post-treatment healthcare can be most effective only when patients feel secure and trust the healthcare facility completely. Suppose there is no more trust in a secure system that protects privacy and health information, which can impact family life and social interactions (with friends, at work, etc.). Patients may be reluctant to provide and share health information with medical practitioners. As a result, doctors cannot accurately diagnose or provide the most effective treatment regimen (Belfrage et al., 2022). Therefore, the approach to protecting patient information is to build trust, allowing patients to share it proactively.

Conversely, current regulations such as the Civil Code, Law on Protection of Personal Data approach it by recognizing the right to privacy, subjecting personal data, prohibiting acts, and protection measures through criminal, administrative, and civil sanctions. Post-breach legislation (Hereinafter "post-remedy") aims to restore and compensate for material and spiritual losses of those whose privacy/personal information rights have been violated. However, post-remedy regulations have not approached patients' real wills and desires. Regarding privacy and sensitive personal information, nobody wants a violation to occur, and post-remedy rules are applied to compensate for spiritual losses. Moreover, the time and monetary costs of pursuing compensation lawsuits have always been challenging for patients in Vietnam (Tran Ngoc Tuan, 2022). Therefore, the rules on the responsibility to protect the information confidentiality of data processors as stipulated in Law on Protection of Personal Data and the obligation to protect consumer information confidentiality of individuals/business organizations as specified in the Law on Consumer Protection (post–remedy) is not enough to cover given the specific nature of the relationship between patients and healthcare facilities. The approach and purpose of the legal regulations regarding the obligation to protect the confidentiality of health information in healthcare facilities must be identical to those of consumer law (Thierry Vansweevelt & Nicola Glover-Thomas, 2023).

Although Art. 45 (5) of the Law on Medical Examination and Treatment 2023, stipulating the obligations of practitioners to the profession, has affirmed the obligations of individual medical practitioners in keeping *the confidentiality* of patients as follows: "Keep confidential *the patient's medical condition*, the *information provided by the patient* and *the medical record*, except for the case where the patient agrees to share the information and the cases specified in Clauses 3 and 4, Article 69 of this Law", the Law on Medical Examination and Treatment and other guidelines from the Ministry of Health do not address healthcare institutions' obligations to secure personal data in healthcare activities. To be more specific, there are currently only a few sub-law documents regulating the responsibility of healthcare facilities to protect the confidentiality of patient health information in telehealth activities. For example, Art. 87(1)(d) of Decree 96/2023 requires healthcare institutions to fulfill the conditions for conducting telehealth. These conditions include suitable technical infrastructure, IT equipment, specialized equipment, and IT software programs that can transmit, display, process, and store data safely and confidentially; additionally, data storage and backup periods must comply with legal regulations.

Therefore, it can be affirmed that (1) in the Vietnamese medical sector, there are currently no general regulations on the obligation of healthcare institutes to provide secure health information for medical examination and treatment facilities to prevent harmful acts. Especially in the context of AI implementation, there are no regulations or guidelines instructing healthcare facilities to establish information security systems and train high-quality human resources with awareness and skills to prevent the disclosure, improper use, and unintentional sharing of patient information.

(2) Medical facilities that lack regulation commit to providing patients with information about collecting, using, and sharing information for the correct purpose. In Vietnam, there are no specific regulations that require healthcare providers to inform patients how their data is handled. Due to the prevalence of AI devices in healthcare, many patients may lack knowledge about AI mechanisms and the potential risks these technologies pose to their personal information. Limitations within the legal framework increase the risk of disclosing sensitive personal data without the patient's informed consent. If patient self-determination faces risks, especially AI devices that collect, process, and use patients' personal information, this concern goes beyond legal obligations and encompasses ethical considerations. As a result, regulations on personal data protection must be updated, including provisions that require healthcare providers to provide necessary information and obtain patients' informed consent regarding the use, access, and control of their data.

(3) Lastly, the life cycle of AI is very different from that of traditional devices and software. At the stage of AI development, the data entry stage for machine learning poses a potential risk of personal information infringement. Therefore, to protect the sensitive personal data of patients, not only medical facilities but also stakeholders throughout the AI life cycle must have the obligation or commitment to keep personal health confidential and not infringe upon it, not use personal data for purposes other than the original purpose, and especially must have the consent of the patient when using their personal information. Nevertheless, while many medical oaths and ethics govern privacy concerns for healthcare professionals, there are no similar protections for technology providers. Vietnam lacks regulations regarding patient information confidentiality for tech companies and other service providers to healthcare facilities, including mandatory contract provisions and binding statements of responsibility.

Further Improvements Needed in the Healthcare Sector

The first research on responsible AI in the medical field in Vietnam is relatively late from a global perspective, first mentioned through the workshop "Responsible Artificial Intelligence in the Medical Field," organized by the University of Law, Vietnam National University, Hanoi, on June 21, 2024 (Phuong Lien, 2024).

The responsible development and application of artificial intelligence (AI) in healthcare is crucial. It can revolutionize medical practices by preventing and minimizing risks while promoting the advancement and application of science and technology (Cossy-Gantner et al., 2018). AI technology can analyze medical data, identify patterns, and provide valuable insights to support doctors in making clinical decisions, improving patient outcomes, and reducing healthcare costs. However, the ethical, legal, and social impacts of AI in healthcare must be carefully considered (Sivarajah et al., 2023). The deployment of AI in medical activities must ensure safety, transparency, and fairness (Ayesha et al., 2023). The top priority is to apply AI responsibly, maximizing benefits for all stakeholders while minimizing potential harm. As AI continues to develop, responsible AI research and application will play a significant role in shaping the future of the healthcare sector (Obasa & Palk, 2023).

Responsible AI should be integrated throughout the AI lifecycle, from research and development to deployment and application. Stakeholders (those implementing strategies, planning AI use, managing AI in healthcare decisions, and using AI in healthcare activities) must act ethically and responsibly (Sivarajah et al., 2023).

The goals of responsible AI include: (1) designing and deploying transparent and accountable AI solutions to ensure fairness, which will help healthcare facilities maintain trust when using AI (Santoni de Sio & Mecacci, 2021); (2) enabling healthcare facilities, as AI users, to help patients overcome concerns about AI in healthcare activities, thereby activating the positive effects of AI (Fazakarley et al., 2024); (3) raising awareness among healthcare facilities to minimize violations of patient rights, thus meeting the expectations of stakeholders.

In summary, responsible AI prioritizes the well-being of humans (patients) and aligns with stakeholder expectations while strictly adhering to current legal regulations. The ultimate goal of responsible AI is to balance meeting Patient needs through responsible AI use and achieving long-term economic value for healthcare organizations, aiming for a healthy and sustainable healthcare system (Sivarajah et al., 2023). Vietnam must complete its legal framework to ensure the implementation of ethical AI practices in the healthcare sector. The objectives to be achieved include:

- Respecting the body, life, and health of patients
- Respecting Privacy as a fundamental value and a right, thus requiring data security and protection
- Respecting patient autonomy in choosing AI for healthcare
- Ensuring fairness and non-biased in developing healthcare algorithms
- Establishing clear legal responsibilities when using AI in healthcare

Not only is it necessary to establish guidelines on the principles of responsible development and research of artificial intelligence in the medical field, but it is also crucial to develop detailed and transparent regulations, particularly for aspects that require legalization (referred to as "hard law").

In other words, besides guidelines, such as soft laws issued by associations, should guide medical examination and treatment facilities strictly complying with legal regulations, thereby minimizing risks and creating benefits for all stakeholders, legal rules on processing, sharing, and using patient health data in medical activities must be developed in the context of digital transformation in general.

Despite current regulations attempting to address the increasing use of AI, regulatory gaps still need to be filled to ensure its safe, effective, and ethical use. Specifically, in healthcare services, AI risks need specific regulations to ensure patient safety and improve healthcare services (Meskó & Topol, 2023). As analyzed above, to address the current problems in Vietnamese law and move forward to implement responsible AI in the medical sector, Vietnam needs to complete two crucial legal documents immediately.

One is to amend and supplement the Decree on medical devices.

Indeed, AI algorithms in medical devices (MD) that can self-learn and adapt may introduce new and unknown risks, potentially surpassing the initial risks identified by developers and regulators. Vietnam's current medical device regulations must be more suitable for AI-enabled medical devices. Like other jurisdictions, Vietnam needs to develop rules regarding approval standards for AI-MD to ensure patient safety and build trust among stakeholders willing to research, develop, and use new technology products.

The second is to issue a new decree on the Protection of Personal Health Data.

Vietnam is aiming to synchronize personal data, especially in the context of digital transformation. With the development of 4.0 technology trends, the application of AI in the healthcare sector in Vietnam is gaining increasing affirmation. Vietnam is gradually implementing digital solid transformation, which, on the one hand, brings numerous benefits to the healthcare system, but at the same time, creates new risks of infringing on Privacy and personal data. The application of AI in disease diagnosis through imaging creates more data demands. Data collection, use, storage, sharing, and management raise many ethical and legal questions related to Privacy and personal data in the relationship between healthcare facilities and patients. There are no common criteria and standards for healthcare facilities to protect patients' privacy, which builds trust-based relationships between patients and healthcare facilities. Therefore, protecting Privacy in the healthcare sector in Vietnam, in the context of digital transformation, is hindered by the absence of a legal framework on the obligation to protect the confidentiality of healthcare facilities' health information in the Law on Medical Examination and Treatment 2023. Personal Health Data Protection Decree must be contented several following contents but unlimited : (a)Conceptual content of patient personal data (paying attention to new data in the 4.0 era); (b) Methods of data transmission and collection in the context of AI; (c) The obligation to protect the information of medical examination and treatment facilities is specified as the obligation to establish infrastructure, the commitment to train appropriate human resources; (d) The rights and obligations of related parties (including technology enterprises, service providers - partners of medical examination and treatment facilities but not limited to); (e) Affirming that informed consent of patients must be recorded - a related concern is ensuring that appropriate consent models have been used to obtain permission to use personal patient data, the obligation to provide information of related parties to patients to ensure the collection, use, and sharing of personal information is within the authority; (f) Exemptions that do not require patient consent should also be considered, and they should be considered in specific cases appropriate to the medical field.

CONCLUSION

The article highlights Vietnam's policy to develop AI in the healthcare sector, and practice shows that many healthcare facilities have adopted AI in their activities. However, Vietnam still needs to assess the impact of AI on society and legal issues. Regarding ethics, Vietnam can accept research from countries that have developed and used AI in healthcare to identify immediate risks and take measures to limit them. To reduce risks, practicing responsible AI in healthcare is essential as the system moves toward human-centered and sustainable development. To accomplish this, it is crucial to research and evaluate current laws considering the changes brought by AI in healthcare. This research emphasizes the importance of regulation and policy considerations. Based on ethical principles of responsible AI, the study also shows that Vietnam's current legal system lacks regulations on developing and deploying AI in healthcare. The final outcome offers recommendations for Vietnam to build a people-centered health system in the new era through reform and the creation of relevant laws such as Health Data Protection and AI-Medical Devices.

Conflict of Interest

The author have declared no conflict of interest.

Funding

This research was carried out under the project QG.25.164 "Law on Protecting Patients' Rights in the Context of Development and Application of Artificial Intelligence and Digital Transformation," funded by Vietnam National University, Hanoi, Vietnam.

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