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VIETNAMESE ETHICAL AND LEGAL CHALLENGES IN PROTECTING PATIENT PRIVACY THROUGH INFORMED CONSENT

DESAFIOS ÉTICOS E JURÍDICOS DO VIETNÃ NA PROTEÇÃO DA PRIVACIDADE DO PACIENTE ATRAVÉS DO CONSENTIMENTO INFORMADO

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Abstract
This article examines the relationship between patients and healthcare facilities or medical practitioners through the lens of informed consent, emphasizing the patient's right to informational privacy, which includes personal and health-related data. From the perspective of the 2023 Law on Medical Examination and Treatment and the 2025 Law on Personal Data Protection, the article presents objective arguments highlighting the need to protect patients' rights in the processing and sharing of personal and health information. These arguments are grounded in both ethical principles and legal justifications. However, under the current Vietnamese legal framework, patients' rights to keep their health information confidential are not fully protected, especially regarding informed consent. This insufficient legal protection may hinder the growth of the healthcare system, particularly in the era of digital transformation.

Keywords: Bioethics. Patient Privacy Rights. Informed Consent. Vietnamese Healthcare Law.

Resumo
Este artigo examina a relação entre pacientes e instituições de saúde ou profissionais médicos sob a ótica do consentimento informado, enfatizando o direito do paciente à privacidade das informações, o que inclui dados pessoais e relacionados à saúde. A partir da perspectiva da Lei de 2023 sobre Exames Médicos e Tratamentos e da Lei de 2025 sobre Proteção de Dados Pessoais, o artigo apresenta argumentos objetivos que destacam a necessidade de proteger os direitos dos pacientes no processamento e compartilhamento de informações pessoais e de saúde.
Esses argumentos são baseados em princípios éticos e justificativas legais. No entanto, sob a atual estrutura jurídica vietnamita, os direitos dos pacientes de manter suas informações de saúde confidenciais não são totalmente protegidos, especialmente no que diz respeito ao consentimento informado. Essa proteção jurídica insuficiente pode impedir o crescimento do sistema de saúde, particularmente na era da transformação digital.

Palavras-chave: *Bioética. Direitos de privacidade do paciente. Consentimento informado. Lei de Saúde do Vietnã.*

1 INTRODUCTION

One of the main concerns shared by countries worldwide is healthcare. It is also widely recognized as one of the most strictly regulated industries *(1:2).* From an ethical perspective, the healthcare sector comprises a complex network of legal relationships

governed by multiple legal frameworks. However, the primary focus of all these regulations remains the same: the human being—the patient *(2, 3, 4).*

In the discourse on patients' rights, two fundamental categories emerge: (i) the right to bodily integrity, life, and health; and (ii) the right to health-related and personal information (i.e., personal data and privacy). Any decision concerning these two core rights must ultimately rest with the rights-holder—the patient. The patient's autonomy in making decisions about their own person must be respected. In both medical and legal contexts, this principle is encapsulated in the concept of "informed consent." *(5).*

This article focuses on the patient's right to consent to the processing and sharing of personal and health-related information, as regulated by Vietnam's Law on Medical Examination and Treatment 2023 (*6)* and the Law on Personal Data Protection (LPDP*) (7).* Through an analysis of the relevant legal provisions and their practical implementation, this study finds that although Vietnam has established legal grounds for patient consent regarding the use, processing, and disclosure of health information—both under the obligations of healthcare practitioners and the rights of patients, and within the newly enacted general legal framework for personal data protection—there remain significant gaps in the legislation. These shortcomings have contributed to inadequate recognition of patients' consent rights in practice, a situation that is likely to deteriorate further in the context of ongoing digital transformation.

2 INFORMED CONSENT: ETHICAL AND LEGAL FOUNDATIONS IN MEDICAL PRACTICE

2.1 From an ethical perspective

Informed consent is a process of interaction between healthcare professionals and patients in which the medical practitioner provides full and comprehensible information about the patient's health condition and the methods by which the healthcare facility or practitioner collects, processes, uses, stores, and shares the patient's health information *(8).* The ultimate goal is to enable patients to make informed decisions in accordance with their right to self-determination—whether to accept or refuse treatment, to provide personal information, and to control the use of their health data *(9).*

The principle of informed consent in medicine is grounded in core ethical values, including respect for autonomy, which affirms that patients have the right to make decisions about their bodies, health, and personal data, including health-related information *(9, 10)*. Physicians have a duty to provide the best possible healthcare services to their patients while being obligated to maintain the confidentiality of health information and to respect patients' decisions *(11)*. This means not infringing on privacy or personal data and refraining from any use or disclosure of patient information beyond treatment purposes without the patient's explicit consent *(12)*.

Informed consent promotes and ensures justice in patient care *(13)* and builds trust by informing patients and involving them in decision-making, particularly regarding the control, use, and sharing of their personal data *(14)*. It also helps prevent misuse or unethical disclosure of patient data for purposes unrelated to direct care, such as unnecessary or unjustified medical research *(14)*. Informed consent is a fundamental requirement for conducting ethical research, ensuring that medical studies respect the rights and dignity of research participants *(15)*. Finally, informed consent helps mitigate the risk of litigation, as patients who are actively engaged and empowered to control how their data is processed, stored, and used are less likely to pursue legal action *(15)*.

2.2 From a legal perspective

In most jurisdictions, informed consent is recognized through explicit statutory provisions or judicial precedent *(11)*. Noncompliance with the principle of informed consent may result in serious legal consequences *(16: 108)*. In particular, the unauthorized use of a patient's medical data by healthcare institutions or medical practitioners—without the patient's consent—may constitute a violation of data protection laws and an infringement of the individual's right to privacy regarding personal health information *(11)*.

2.3 Patient's informed consent under Vietnamese law

2.3.1 Patient consent under the medical examination and treatment law

Under patients' rights and the obligations of medical practitioners (Article 45(5) of the Law on Medical Examination and Treatment 2023), the Law permits the disclosure of patient information, health status, and medical records when the patient has given consent. However, the Law on Medical Examination and Treatment 2023 does not provide a specific legal framework for the nature of such consent—including its legal characteristics, modalities, forms of expression, validity, or duration. The absence of a clear and comprehensive legal framework to define and regulate patient consent may lead to arbitrary practices regarding the use, disclosure, or transfer of patients' personal information (*3:37, 17)*. This legal gap raises the critical question of whether patient consent in Vietnam genuinely reflects autonomous will and informed decision-making—based on an assessment of personal rights, benefits, and potential risks—or whether it exists merely as a formal requirement lacking substantive meaning *(18).*

2.3.2 Patient consent under law on personal data protection

To address the regulatory gap in the Law on Medical Examination and Treatment 2023, the Law on Personal Data Protection (LPDP) is currently regarded as the principal legal framework safeguarding patients' privacy by formalizing and clarifying the concept of "consent" in the context of using and disclosing personal information *(19).* However, a key research hypothesis for this study is whether the general definition of "consent" provided under LPDP is sufficiently robust and specific to govern the unique and sensitive relationship between patients and medical institutions or healthcare professionals.

In practice, applying the law to information about a patient's health condition and personal data raises multiple legal concerns.

First, although LPDP distinguishes between "personal data" and "sensitive personal data," and health-related information falls under the category of sensitive personal data, the legal framework fails to impose differentiated standards or procedures for handling each type *(20:35).* Specifically, while processing sensitive personal data—particularly confidential information concerning an individual's health status—requires

the data subject's consent, Vietnamese law currently lacks detailed provisions for the formal expression of such consent to affirm the subject's explicit will *(20:44).*

Moreover, balancing patients' rights and interests with medical professionals' duties requires informed consent in the patient–healthcare provider relationship *(21:33-34).* Informed consent requires healthcare institutions and professionals to provide clear, detailed information about the purposes, scope of use, potential disclosure, and associated data-processing risks *(8:398).* This is especially critical in the context of digital transformation, as the rapid, often unrestricted flow of information in the healthcare sector demands a reevaluation and rebalancing of patient autonomy *(22:6).*

Second, regarding the processing of minors' personal data, the law requires that such processing be based on the principle of protecting the rights and serving the best interests of the child. According to Article 24(2) LPDP: "The processing of a child's personal data requires the child's consent if the child is 7 years of age or older, and also the consent of the parents or legal guardian, unless otherwise provided in Article 19 (1) of this Law." However, this provision is ambiguous and may lead to considerable difficulties in implementation.

The possible interpretation is that the legislator uses age 7 as a threshold for differentiation as follows: (i) For children aged 7 or older, both the child's consent and that of the parents or legal guardian are required; (ii) For children under 7, although no explicit regulation is provided, it implies that parental or guardian consent is sufficient and the child's consent is not necessary.

This interpretation introduces its own set of inconsistencies. For example, adolescents between 15 and under 18 years old—who are often mentally and physically capable of making autonomous decisions—would still need parental consent to authorize the processing of their personal data. This raises questions about the proportionality and appropriateness of such a requirement.

From a practical standpoint, some medical institutions have stricter privacy policies that require parental consent for all minors (under 18 years of age). For instance, Vinmec International General Hospital's privacy policy states: "For customers under the age of 18, please ensure that full consent and approval from a parent or legal representative has been obtained... The hospital reserves the right to refuse access to the Vinmec Channel or to provide related services if there is reason to believe that the

customer under the age of 18 has not received the necessary consent and approval from a parent or legal representative." *(23).*

This shows that, in practice, medical facilities are applying the Law on Medical Examination and Treatment by requiring parental consent for all minor patients. However, such a blanket approach may not ensure minors' access to healthcare or respect the self-determination rights of legal subjects who are otherwise capable of exercising their autonomous will and making decisions about their personal information, privacy, and health.

Third, Vietnam currently lacks legal provisions governing the disclosure of a patient's medical information after death. Consequently, violations of posthumous medical privacy rights are relatively common in life insurance disputes. Several legal questions arise under Vietnamese law regarding a deceased patient's medical information. First, do life insurance companies have the right to collect deceased clients' medical records? Second, when requested, are medical institutions permitted to disclose deceased patients' medical records to insurers? Vietnamese legislation does not provide clear regulations on this matter. Thus, the disclosure of medical records to insurance companies is subject to the hospital director's discretion *(24).*

In practice, many court decisions demonstrate that insurance companies can obtain and submit clients' medical records as evidence to deny compensation claims. Courts admit and consider such records as valid evidence *(25).*

This raises serious concerns. In practice, the disclosure of medical records may still occur despite the absence of a clear legal framework regulating the collection and use of deceased individuals' sensitive personal data. Vietnam does not yet have a specific statute that prohibits or governs the posthumous use of such medical records as legal evidence, particularly in the context of life insurance litigation.

3 REGULATIONS ON PROCESSING PERSONAL DATA WITHOUT THE DATA SUBJECT'S CONSENT

3.1 First Scenario - prevention of harm to patients or others

In emergencies where it is essential to process personal data immediately to protect the life or health of the data subject or another individual, the Personal Data

Controller, Personal Data Processor, Controller-cum-Processor, and any Third Party bear the burden of proof in demonstrating the necessity of such circumstances (Art. 19(1) a). Nevertheless, applying this exception to sensitive personal data, such as health information, raises significant concerns about protecting patient privacy. In other words, the provisions concerning consent and the exceptions to consent, as stipulated in LPDP, are not entirely compatible or adaptable when applied to the context of health-related information of data subjects.

For instance, consider disclosing a patient's health information to a third party for the benefit of that party. If a physician informs and discloses a patient's HIV status to the patient's spouse to protect the spouse's health, can such conduct be shielded from liability for breaching professional obligations (specifically, the duty to maintain patient confidentiality)? This remains a controversial and critical question for both legal theory and practice.

3.2 Second scenario - national defense, national security, public order and safety, major disasters, and dangerous epidemics

Processing of Personal Data by State Authorities in Cases of Emergency Related to National Defense, National Security, Public Order and Safety, Major Disasters, and Dangerous Epidemics (Art. 19 (1) b of LPDP). The processing of personal data by competent state authorities is permitted in situations such as national defense emergencies, threats to national security, public order and safety, major disasters, or dangerous epidemics. This also applies when there is a risk that national security threats do not reach the threshold for declaring an emergency, as well as to preventing and combating riots, terrorism, crime, and other violations of law, in accordance with statutory provisions (Public Interest).

However, it must be clearly recognized that although data used for public interest purposes may be disclosed, personal data must, as a rule, be anonymized unless the matter concerns national defense and security *(26:24).* As in other jurisdictions, Vietnam seeks to balance private interests with the public interest. In the context of a pandemic, the disclosure of data to competent state authorities within the healthcare system is necessary and does not require the patient's consent.

Nevertheless, Vietnam has not clearly distinguished between (i) health-related information essential for public health purposes that should be utilized, and (ii) individually identifiable personal information that must be protected. As a result, Vietnam currently lacks a legal mechanism to effectively anonymize or encrypt each patient's personal data.

During the pandemic, disclosing the identities of COVID-19 patients raised significant legal concerns about the use and potential manipulation of personally identifiable information. Numerous leaked images of documents, allegedly rapid reports from healthcare facilities to competent authorities regarding COVID-19 cases, circulated widely.

It is crucial to understand that, while the collected and processed data serve critical public health interests, a strict separation must be maintained between the information necessary for public health protection and the private information of individual patients *(26:24).*

3.3 Third Scenario - serving the operations of state agencies and state management activities in accordance with the law

Under Vietnamese law, LPDP personal data may be processed to support the operations of state agencies and state management activities in accordance with the law (Art. 19 (1) c) and to implement the agreement of the personal data subject with relevant agencies, organizations, and individuals in accordance with the law (Art. 19 (1) d).

However, this raises several questions about the scope of services for state agencies' operations and state management activities in accordance with the law. In the field of healthcare, statutory exceptions are explicitly outlined in Article 69 of the Law on Medical Examination and Treatment 2023, particularly in Clauses 3 and 4, as follows:

Article 69 (3) stipulates that access to medical records during ongoing treatment will be as follows:

a) Students, trainees, interns, and researchers from research or educational institutions, as well as healthcare practitioners and individuals directly involved in the patient's treatment within the medical facility, may read the records but may make copies only with the consent of the medical examination and treatment facility.

b) Practitioners from other medical facilities may read and copy medical records only after obtaining consent from the medical examination and treatment facility.

Article 69(4) provides that access to medical records that have completed the treatment process and are archived shall be implemented as follows:

c) Representatives of competent state management authorities in the health sector, investigative agencies, the procuracy, courts, health inspectorates, forensic medical institutions, forensic psychiatric institutions, and legal representatives (lawyers) of the patient shall be granted access to and provided with medical records to perform their statutory duties.

d) Students, trainees, interns, researchers affiliated with research or training institutions, and practitioners employed at the medical facility may borrow, read, or copy medical records on-site for research or technical professional purposes, provided they obtain consent from the medical examination and treatment facility.

e) Representatives of social insurance agencies and those responsible for state compensation may borrow and review medical records on-site, take notes, or request copies to fulfill their assigned duties, provided they obtain consent from the medical examination and treatment facility.

Moreover, this raises several questions about the scope of the contractual obligations data subjects have agreed to. The regulation appears to create a loophole in practice. For example, it has been interpreted to allow the provision of health information to fulfill obligations under an employment contract. In practice, it is common for companies to arrange annual health check-ups for employees at medical institutions under service contracts, with the examination results returned to the employer rather than directly to the employee.

Moreover, there have been instances in which insurance companies obtained medical records from employers to use against policyholders in disputes over insurance claims *(27).*

One of the root causes is the lack of recognition in Vietnam of the patient's privilege in the relationship between patients and healthcare providers. In contrast, in some jurisdictions, patient privilege is recognized by law to protect medical confidentiality. For instance, the Delaware Uniform Rules of Evidence codify the Hippocratic Oath by specifically acknowledging the doctor-patient privilege in litigation *(28:1).*

In such jurisdictions, even physicians or medical institutions are prohibited from using patients' personal information to defend themselves in court, let alone from providing it to third parties to fulfill a patient's contractual obligations. With this privilege, patients have the right to refuse the admission of evidence based on medical information provided by healthcare institutions.

Given the advancement of technology and the increased risk of personal information being disclosed during court proceedings, a crucial question arises: *Should Vietnam recognize the patient's privilege in the relationship between patients and physicians?* Without such a privilege, personal health information could be disclosed publicly during trials and subsequently republished multiple times through print and electronic media, including the Internet *(29:2).*

4 CONCLUSION

It can be observed that Vietnamese law has not historically established a strong tradition of protecting patients' rights, including the right to privacy of health information *(30:14).* However, in recent years, significant legislative efforts have been undertaken to gradually strengthen the legal framework for privacy protection, particularly through the promulgation of the LPDP. In the healthcare sector, patients' rights have also been elevated through the enactment of the amended Law on Medical Examination and Treatment 2023.

These legislative advancements strengthen the protection of patients' personal and health information *(31: 1958).* Nevertheless, an examination of the concept of "informed consent" reveals that patients' rights—especially the right to privacy—have not been fully recognized in light of the substantive nature of the relationship between patients and healthcare providers/medical institutions. As a result, the legal provisions governing patients' rights and the obligations of physicians, healthcare facilities, and other stakeholders have not fully met the requirements for effective implementation in practice, particularly with respect to the exercise of patients' rights in general and privacy rights in particular.

Moreover, with the exponential growth of healthcare data driven by the digitalization of medical information, the need to safeguard health information and protect privacy has become increasingly critical *(31: 1959).* Accordingly, Vietnam must

continue to strengthen its legal framework to build a comprehensive healthcare system, thereby aligning with a key objective of sustainable development.

RIGHTS AND PERMISSIONS: OPEN ACCESS

AUTHOR'S DECLARATIONS AND ESSENTIAL ETHICAL COMPLIANCES

The author is solely responsible for all aspects of this work, including conception, design, data collection, analysis, and manuscript writing.

COMPETING INTERESTS/CONFLICT OF INTEREST

The author has no competing financial, professional, or personal interests from other parties or in publishing this manuscript. There is no conflict of interest with the publisher, the editorial team, or the reviewers.

DECLARATION OF THE USE OF AI

During the preparation of this work, the authors have used Grammarly [AI] to assist with proofreading. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the published article.

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Authors' Contribution

All authors contributed equally to the development of this article.

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All datasets relevant to this study's findings are fully available within the article.

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