

Digital Healthcare in Vietnam: Current legal framework and recommendations in comparison with some ASEAN countries

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I. The Vietnam's context and the role of the law in Digital Healthcare

While most industries are gradually transforming following the wave of digitization and technology, the healthcare landscape in Vietnam is also not immune to this trend. Over the past decade, Vietnam has made significant progress on key indicators of quality of life, such as reduction in maternal, under-five, and infant mortality; life expectancy at 76 years – higher than most countries in the region; and easier access to affordable medicines. Regarding universal health coverage (UHC), 90% of the country's population is covered with health insurance and is targeted to reach 100% in 2030.

However, many challenges remain. A patient in Vietnam may face several pain points throughout his healthcare journey, from accessibility, quality, cost and overall experience. According to statistics in 2021, Vietnam has 3.07 beds and 0.9 doctors per 1000 people which results in frequent oversubscription and overcrowding, especially in government-funded hospitals that still predominate in the country. Also, 65% of Vietnam's residents are located in rural areas, but most want to be treated at central hospitals, making their access to healthcare geographically limited and time-consuming.

On the other hand, Vietnam's rapid population and economic growth have generated a new middle class with a demand for higher-quality medical care. These affluent, digitally-literate consumers are spending more on their healthcare, leading to a rise in demand for private

providers and digital health services. The population of Vietnam is not just becoming wealthier, it is also getting older. The outcome of this is a shift of disease burden from communicable to non-communicable conditions like diabetes and cancer, requiring coordinated, long-term care solutions.

Thus, digital healthcare is seen as an answer for the health system of Vietnam to provide more services without expending overmuch resources as well as achieve scale of access while enhancing clinical efficiency and maintaining costs. Meanwhile, Vietnam is embracing the 4th Industrial Revolution with an explosion of the internet and technology. Building on such a strong digital foundation, the Vietnamese government is driving a digitalization agenda in hospitals and clinics all over the country. Smart solutions using artificial intelligence (AI), big data, cloud computing, blockchain and mobile technology are gradually being applied. Vietnam is on the way to transitioning from a paper-based medical records system to a digital system. The Deputy Director of the Information Technology Department under the Ministry of Health once announced that Vietnam is the concept of "3-no's hospital" - No papers, No queues, No cash payments.

In Vietnam, for the digital healthcare, the law plays an important role.

Firstly, due to the unique role and power of the law: There are many different tools to regulate behavior, but the law has its own strengths, due to its common normative nature, affecting the target group the most widely in society. The law is guaranteed by the power of the State, including coercive enforcement or organizational and advocacy measures. With a strong advantage over other social norms, through legal regulations, the implementation of digital healthcare will be better. Especially for developing countries, the law plays an important role in regulating healthcare activities¹.

Second, due to the context of Vietnam: being a country with a written law, the interpretation of the law by the courts is still based on written law. Only very recently have precedents been admitted in modest numbers. Therefore, when adjusting social issues, it is necessary to have a

¹ [Roger S Magnusson](#), [Benn McGrady](#), [Lawrence Gostin](#), [David Patterson](#), and [Hala Abou Taleb](#), Legal Capacity required for prevention and control of non communicable diseases, [Bull World Health Organ.](#) 2019 Feb 1; 97(2): 108–117. Published online 2018 Nov 20. doi: [10.2471/BLT.18.213777](https://doi.org/10.2471/BLT.18.213777)

complete and specific legal framework. Digital healthcare also needs to be based on specific legal rules to easily come to life.

And the digital transformation has become a policy in many activities of the State of Vietnam in recent years – for example the e-Government model. Legal regulations on digital transformation in State activities have been promulgated. Online public service models have been deployed. Based on that common legal system, the concretization of legislation in healthcare will be more systematic and methodical.

In this article, we present about Vietnam's digital health regulations, the vision and policies of the government, as well as lingering concerns that must be addressed for the full growth of the medical industry.

II. Overview of legal regulations related to Digital healthcare in Vietnam

1. Applicable laws / regulations

- 1.1. Regarding digital transformation in general, the Government of Vietnam has made certain positive moves to integrate into the era of information technology and data, starting from the transition from traditional government to building E-Government and towards building a Digital Government. From 2019 to now, the Government has issued many directives related to this task, specifically:

2019: Resolution No. 17/NQ-CP on a number of key tasks and solutions to develop e-Government in the period of 2019 - 2020, with orientation to 2025.

2020: Decision No. 749/QD-TTg approving the National Digital Transformation Program to 2025, with orientation to 2030.

2021: Decision No. 942/QD-TTg approving the e-Government development strategy towards digital government in the period of 2021 - 2025, with orientation to 2030.

And most recently, on **April 2022**, Deputy Prime Minister Vu Duc Dam signed Directive No. 02/CT-TTg of the Prime Minister on developing e-Government towards digital government, promoting transformation change country number.

- 1.2. However, when it comes to digital health, Vietnam still lacks a clear and solid definition in the law:

Digital health is defined in the Decision No. 4888 as *“the next step of e-health, which focuses on collection and utilization of healthcare data via application of digital technologies in activities of the healthcare sector”*.

Healthcare digital transformation is defined in Decision No. 5316 as *“an overall and comprehensive application of information technology with special focus on modern digital technologies that can make positive changes in the entire medical practice in healthcare”*.

Besides, Vietnam law also has the definition of **telemedicine** specified in Circular No. 49 as *“exchange of information related to a patient’s health between such patient and a healthcare provider or among healthcare providers in distant areas through the use of information technology (IT) and telecommunication”*.

- 1.3. Digital healthcare in Vietnam recently is guided by several key policies issued by the Ministry of Health (MoH), namely:

Circular No. 53, 2014: sets forth the requirements for the provision of online healthcare services including provision, transmission, collection, processing, storage and exchange of health information using information technology.

Circular No. 54, 2017: stipulates the assessment criteria for information technology applications at healthcare facilities across Vietnam include 8 groups: IT Infrastructure, Administration And Operation Software, Hospital Information System, Radiology Information System - Picture Archiving And Communication System, Laboratory Information System, Nonfunctionality standards, Security and information safety, Electronic Medical Record.

Circular No. 49, 2017: covers certain issues including requirements, especially in technical and IT, that must meet by those engaging in distance medicine; applicable licenses and qualifications; as well as provides guidelines on a range of telemedicine

activities such as telemedicine advice and consultation, teleradiology consultation, remote anatomy consultation, remote surgery consultation and telemedicine technology transfer training.

The key provisions of Circular No. 49 include:

- (i) Telemedicine activities may only take place at facilities properly licensed under the Law on Health Examination;
- (ii) IT infrastructure and information safety and security measures must fully satisfy the conditions specified in Circular No. 53; and
- (iii) For medical diagnosis consultation involving images, the transmission of images must be on a 4Mbps or faster line, with additional regulations on the storage and compression of images.

Circular No. 4888, 2020: approves the Program for health digital transformation until 2025 and orientation to 2030. The circular provides the definitions of “e-health”, “digital health” and “smart health”; and outlines development goals for the healthcare industry in the context of the Industrial Revolution 4.0. The MOH has outlined a roadmap for patient records digitalization at hospitals and smart hospitals establishment. This is the beginning of an ambitious multidisciplinary journey that will benefit from access to the global industry’s best practices.

The following goals are specified:

- (i) Developing a smart health care and disease prevention system
- (ii) Promoting IT implementation in health facilities for administrative process improvement and reducing hospital overload: adopting EMRs to replace paper records, using a cashless payment system for hospital billings, and establishing smart hospitals
- (iii) Promoting IT implementation in health administration: installing the electronic office system, public portals, and single-window information system of administrative procedures, promoting level 3 and level 4 web-based public service, building a smart health administration

To achieve these goals, the scheme proposes 9 following areas of action from 2019 to 2025:

- (i) Building the regulatory framework, guidance, standards, and economic–technical norms
- (ii) Building the health IT infrastructure
- (iii) Building a smart health care and disease prevention system
- (iv) Building a smart health care system
- (v) Building a smart health administration system
- (vi) Developing the workforce
- (vii) Promoting smart health IT research, development, and implementation
- (viii) International cooperation
- (ix) Educating the public’s awareness of smart health care

Decision No. 5349, 2019: approves the Plan for deployment of electronic health records (EHR).

The primary contents of the Decision include:

- (i) EHR software development,
- (ii) healthcare identification number assignment for each EHR,
- (iii) information and data management.

EHRs are recognized as a tool to connect patients with medical staff, connect medical facilities with each other and with social insurance, contributing to the realization of digital health, and promoting the active role of each individual in health care and disease prevention.

Decision No. 5316, 2020: approves the Healthcare Digital Transformation Scheme until 2025 and orientation to 2030, promoting the implementation of information technology and digital technology all aspects of healthcare activities. The key 4 areas addressed in this scheme are state administration, cashless payment and telehealth, disease prevention and primary care, and health care. In the health care area, the scheme aims for 15% (210/1400) and 50% (700/1400) of hospitals in the country to successfully adopt paperless EMRs and cashless payment by 2025 and 2030, respectively.

Recently, the Project on telemedicine for the period 2020-2025, issued under Decision No. 2628/QD-BYT dated June 22, 2020 of the Minister of Health, has been put into operation for testing purposes: building a remote medical examination and treatment system

2. The agencies responsible for implementing DH in Vietnam

In Vietnam, the main regulatory body is the IT Department at the Ministry of Health, which gives guidelines on and inspects digital health activities, and cooperates with other state agencies to implement state management of digital health. The Ministry of Health may work with other agencies if issues around network security or breaches are raised under the Law on Network Information Security.

Vietnam's mechanism is similar to Thailand. In Thailand, the Ministry of Public Health is the main regulator for health matters—including medical devices, which would include digital health activities².

But this mechanism is different from Indonesia: In Indonesia, there is no single regulatory body in charge of digital health. Two ministries are particularly relevant. The Ministry of Health formulates and implements health and technical policy relating to public health, health services, pharmacy, health technology, and medical devices. The Ministry of Communications and Information Technology regulates communications, information affairs, and internet censorship³.

III. Current situations of digital healthcare in Vietnam

The government's concerted effort to modernize the health system has brought about milestone achievements for digital health:

1. Utilization of information technology in medical services

IT has been installed and used in some central hospitals since the 2000s. The national electronic communicable disease surveillance system (eCDS), developed in 2004, was the first nationwide attempt to computerize surveillance data.

² <https://www.tilleke.com/insights/digital-health-in-thailand-vietnam-and-indonesia/> , <https://www.tilleke.com/> july 20th 2022.

³ <https://www.tilleke.com/insights/digital-health-in-thailand-vietnam-and-indonesia/> , <https://www.tilleke.com/> july 20th 2022.

By 2012, the national health information infrastructure had been put into trial in health facilities and hospitals to support archiving hospitals' administrative data; receiving complaints from patients; controlling disease; connecting, synthesizing and analyzing medical data.

A vital development took place in July 2019, when Vietnam launched its electronic medical records database nationwide. Until now, 100% of public hospitals have installed hospital information systems.

At the present time, The MOH, coordinated with Vietnam Social Security (VSS), has linked 99.5% of the medical facilities in Vietnam under the medical supervision system of VSS.

2. Medical mobile applications:

Vietnam has seen a plethora of digital health applications as of the outbreak of COVID-19. Some major mobile apps to mention are:

NCOVI and Vietnam Health Declaration: record electronic health declarations of domestic and international travellers for the purpose of case monitoring and surveillance.

Bluezone: a COVID-19 contact-tracing app using Bluetooth low energy (BLE) to identify people who have been in close contact with COVID patients. Regarding several data privacy-related concerns, the developer of Bluezone has announced that the application only saves data on the user's phone, does not transfer it to the system, and does not collect the user's location. All the collected information of one user is anonymous to others. Only competent health authorities have the power to access the data storage.

Apart from dealing with the global pandemic, there are other medical apps that have proved to be successful in the Vietnamese market, even used by the elderly generation, such as: S-Health, Blood PressureTracker, ThuocSi, etc.

3. Telemedicine:

Like medical mobiles, although has been deployed since 2003, Telemedicine has only recently demonstrated its role and benefits in the COVID-19 epidemic:

Launched by the AMS on Mar 2020, Telemedicine Centre for COVID-19 Outbreak Control take responsibility for managing resources and providing technical support for health clinics in admitting, quarantining, diagnosing, and treating COVID-19 patients indirectly or virtually, especially for clinics in remote areas. The Center is considered to have great contribution Vietnam's low rate of COVID mortality.

On April 2020, the MOH has announced a telemedicine program aiming to promote virtual medical examination and treatment to mitigate the risk of COVID-19 at the Hanoi Medical University Hospital and several satellite hospitals.

Another program approved by the MoH called "Remote health examination and treatment from 2020 to 2025", after two months of piloting, has successfully connected 1,000 health facilities and clinics in remote mountainous regions with 30 tertiary hospitals in Hanoi and Ho Chi Minh City to provide remote consultation and treatment.

4. Artificial Intelligence (AI), Big Data and Data Management

Vietnam is in the infancy of its use of Artificial Intelligence (AI) and Big Data in healthcare. Some highlights of pioneering AI applications in diagnosis and treatment are:

The VinDr artificial intelligence system, developed by the Medical Image Processing Center (VinBigdata), which enables doctors to diagnose lung diseases on chest X-ray images, breast cancer on mammograms, identify abnormalities on CT/MRI images of the brain, and detect abnormalities on X-ray of the spine been clinically tested at a number of large hospitals such as 108 Central Military Hospital, Hospital Hanoi Medical University Hospital, Vinmec International General Hospital. According to the assessment

from the medical teams of the above hospitals, VinDr has ensured high accuracy, allowing effective support for the general practitioner in diagnosing the disease.

Suit, the People's 115 Hospital and Gia An 115 Hospital. Both of these have adopted the Stanford University "RAPID" system to diagnose and treat strokes.

In cancer diagnosis and treatment, three Vietnamese hospitals are leading the way in terms of digitisation, namely the National Cancer Hospital, Phu Tho General Hospital, and HCMC Oncology Hospital. These three hospitals were selected to participate in the "IBM Watson for Oncology" AI application pilot.

5. The challenges to digital healthare in Vietnam – from lack of legal framework

The booming digital economy creates masses of opportunities for digital health investors. However, according to a Solidiance report, in the 2013–2019 period, the healthcare sector captured just 1% of the total startup funding directed to Vietnam. The noticeable lack of start-ups or M&As in healthcare does not mean there's a lack of interest in this sector, but rather reflects the numerous difficulties that many investors, especially foreign investors, have to face in the execution of healthcare deals in connection with foreign investment ownership, human resources, and unclear regulatory frameworks. Up to the present time, wide-known businesses delivering solutions in the digital healthcare space in Vietnam consist of:

- ✓ Local companies: FPT Information System, VNPT Software, Viettel Business Solutions, VieVie Healthcare, Homecares
- ✓ Foreign companies: IBM, Jiohealth, INFINITT Healthcare, CLAS Healthcare

The challenges posed to DH in Vietnam are many, caused by science, technology, equipment, and human resources, but there are also reasons for the legal framework.

An example in the field of telemedicine. Currently, in Vietnam, there is no clear legal corridor to implement telemedicine.

However, in practice, there is a need for remote medical examination and treatment. The Covid epidemic has made it difficult for people to access medical services. In fact, many people do not go to the hospital for examination, leading to serious illness, even death, because of fear of

infection or fear of being bothered by epidemic prevention measures. During the outbreak, many people infected with COVID-19 had to be treated at home due to overcrowded medical facilities. Stemming from this fact, remote medical examination and treatment services are very necessary and important. This service will contribute to reducing the load on medical facilities and promptly treating patients. However, the law on medical examination and treatment does not provide for the form of telemedicine.

In fact, there have been a number of telemedicine models, but very fragmentary and experimental. There is no uniform legislation. For example, the Ministry of Defense piloted the project "Telemedicine" in 2000 with two hospitals: The Military Central Hospital no 108 (Hanoi) and The Military Hospital no 175 (Ho Chi Minh City); The project of satellite hospital for the period 2013-2020 – given in Decision No. 774/QĐ-BYT dated March 11, 2013 of the Minister of Health. This project has created a satellite hospital network including a number of hospitals under the Ministry of Health. The Department of Health of Ho Chi Minh City, the Department of Health of Hanoi and a number of provinces and central cities specialize in specialties that are currently seriously overloaded such as oncology, cardiology, obstetrics, and fetal medicine. The most recent Project on telemedicine for the period 2020-2025, issued under Decision No. 2628/QĐ-BYT dated June 22, 2020 of the Minister of Health, has been put into operation for testing purposes: building a remote medical examination and treatment system

However, the above projects are only experimental. There is still a lack of a formal legal framework for telemedicine. Due to the lack of legal regulations, many questions remain unanswered. This makes telemedicine difficult to implement in real life.

For example, what are the conditions for telemedicine? Which facilities are allowed to provide medical care remotely? Are facilities allowed to perform all forms of telemedicine? What will medical incident handling look like? Who is responsible when there is a risk in remote medical examination and treatment – the person who directly examines and treats the patient or the instructor? How is the payment for telemedicine activities? In particular, the law on health insurance does not have regulations related to the payment of expenses for this form of medical examination and treatment⁴.

⁴ Department of Medical Examination and Treatment, Ministry of Health (2021), Report on Project implementation of telemedicine, Cục quản lý khám chữa bệnh, Bộ Y tế (2021), Báo cáo thực hiện đề án khám chữa bệnh từ xa

IV. Recommendations to accelerate the development of digital healthcare in Vietnam in comparison with some ASEAN's countries

Generally speaking, it can be seen that Vietnam has adopted and applied digital technology in healthcare at a quite early phase, and the government and the Ministry of Health in particular have made great efforts to promote the digital transformation process.

1. Law is a necessary foundation in the digital transformation of healthcare in order to achieve the health sector's grand goal of improving the health and quality of life of the Vietnamese people while also promoting and providing certainty for businesses. Thus, the Vietnamese government shall devote resources to fortifying the legal framework as well as creating policies to facilitate investors in this field.
2. However, Vietnam is in need of strengthening its legal framework for digital health. Currently, we still do not have adequate standards, regulations and guidelines for telemedicine activities, nor do we have a mechanism for digital health payment schemes from Vietnam's Social Security or private insurance providers. In addition, there is still no legislation specifically governing big data applications and AI health, which would slow down the implementation of these technologies.

In this field, experiences from others ASEAN countries may be interesting. For example, the case of Indonesia. In April 2020, the Indonesian Medical Council issued Regulation Number 74 of 2020 on Clinical Privilege and Medical Practices through Telemedicine during Coronavirus Disease 2019 (COVID-19) Pandemic in Indonesia as a temporary solution during the pandemic. Though in effect only until the end of the COVID-19 state of public health emergency, this regulation allows doctors and dentists to provide healthcare services through telemedicine. Doctors and dentists who perform medical practice through telemedicine must have a registration certificate and a practice license.

This regulation followed a Ministry of Health regulation in 2019 regarding implementation of telemedicine services by health service facilities, which regulates the organization of telemedicine among health service facilities.

The Decision of the Minister of Health No. 4829 of 2021 also provides guidelines for health services through telemedicine during the COVID-19 pandemic. This decision allows the provision of healthcare services remotely through information and communication technologies to enable communication between health service facilities. Specifically, it states that hospitals, public health centers, clinics, independent private medical and dental practices, medical laboratories, and pharmacies are permitted to offer telemedicine services. This regulation remains in effect until the pandemic is officially declared over by the government⁵.

3. Furthermore, another important issue closely related to digital healthcare is the security of personal medical data. Because medical data is personal and sensitive, people are especially concerned about the way their data collected, processed, and analyzed. Information leaks have made people suspicious and lost trust in the government. Meanwhile, although the protection of personal information is a constitutional right in Vietnam, the law on personal data protection is still scattered in many different legal documents without a specific law governing it, causing a lack of unity and centralization.

This raises the urgency of speeding up the completion of propositions such as the Draft Decree on Personal Data Protection or the Draft Decree detailing the Cybersecurity Law.

Particularly in the field of personal data protection in healthcare, it is possible to learn from Thailand's experience

Thailand has for many years considered patient data to be private and has required its handling to be in keeping with general principles of privacy and consent. Until June 2022 this was by way of requirements for licensed healthcare professionals under their professional ethical guidelines. In 2019, the PDPA was enacted, and on June 1, 2022, it took full effect. Now the entire understanding of personal data has taken on more relevance. The PDPA divides regulations between general data and sensitive data, requiring a patient's consent before sensitive personal data can be collected or shared. There are a few exceptions, such as to prevent physical harm to the patient, and use for nonprofit or scientific research purposes.

⁵ <https://www.tilleke.com/insights/digital-health-in-thailand-vietnam-and-indonesia/> , [https://www.tilleke.com/july 20th 2022](https://www.tilleke.com/july-20th-2022).

In Vietnam, The Law on Access to Information stipulates limited access to information, including personal data. However, legal documents specifying the Law can list sensitive data - access to which requires the individual's permission. Courts need specific interpretations of how personal data is protected; exceptions set out for access to personal data⁶

⁶ <https://www.tilleke.com/insights/digital-health-in-thailand-vietnam-and-indonesia/> , [https://www.tilleke.com/july 20th 2022](https://www.tilleke.com/july-20th-2022).