CHAPTER 20 MEDICAL DEVICES AND DIAGNOSTICS

OVERVIEW

The Vietnamese Government has been working to improve the standards of healthcare in the country. Over the past few years, the overall socio-economic situation of Vietnam has also created demand for expanding healthcare services with higher quality. In the past decade, Vietnam's average annual GDP growth has averaged about 6.3 per cent, leading to rising incomes and growing spending on healthcare needs. Meanwhile, rapid urbanisation is putting the healthcare system under high occupancy pressure as major central-level hospitals with high reputations are always fully-occupied. Moreover, life expectancy increased by eight years from 1993 to 2028, rising to 73.5 years, leading to an ageing population. In addition, non-communicable diseases are rising, which now account for 80 per cent of deaths in Vietnam.[1] These trends are expected to continue and will create a greater need for long-term and well-coordinated healthcare services. In light of the fact that the rate of internet penetration is two-thirds of the population and mobile phone adoption is nearly universal, there is huge potential for digital technologies and better machine installation models to be utilised to bring healthcare access to a wider range of people, in a remote manner, and at a better quality.

I. DIGITAL TRANSFORMATION IN VIETNAM'S HEALTHCARE INDUSTRY

Relevant authorities: Office of the Government (OOG), Ministry of Health (MOH)

Issue Description

Over the past decades, the rapid development of technology - especially in healthcare - has been an integral part of people's life. In that context, the Vietnamese Government has committed to a national scheme that seeks to harness the potential of digital solutions across the health system. The Government's vision 2030 for digital transformation in healthcare[2] is to formulate a smart healthcare system based on three pillars[3]:

1. Smart management;
2. Smart hospitals,and;
3. Smart medical record management.

This smart healthcare plan will be built by focusing on different areas:

- The information technology infrastructure serves as the platform for operations management, data collection, reporting system management, and crossed-stakeholder communication.
- Capacity building for the healthcare workforce from the grassroots to central levels.
- A technical and quality assessment framework.
- Data protection and management policy.

1'A Look Forward: How Digitalization is Transforming Vietnam Healthcare System" YCP Solidiance, March 2020. Available at: <https://ycpsolidiance.com/white-paper/a-look-forward-how-digitalization-is-transforming-vietnams-healthcare-system>, last accessed 29 April 2021.

2 Decision 5316/QD-BYT dated 22 December 2020 of the Ministry of Health approving medical digitalization until 2025 and orientation to 2030

3"The health sector promotes the digital transformation to actively participate in the fourth industrial revolution'. Available at <https://ehealth.gov.vn/Index.aspx?action=News&newsId=53443>, last accessed on 27 April 2021.

The current status of digital transformation of the healthcare sector in Vietnam

Since June 2018, Vietnam has set a clear target that, by 2025, 95 per cent of the Vietnamese population will have electronic medical records.[4] While some major progress has been achieved, it is clear that digitalisation in Vietnam's hospitals is yet to be consolidated. Indeed, it is mainly implemented in central-level public and private hospitals, especially in tier-1 cities. Grassroots healthcare providers have limited financial and technical capabilities, hence they have lower e-health readiness and adoption. Digital solutions in hospitals mainly focus on departments such as diagnostic imaging, haematology laboratory, oncology and surgery. However, digital systems among different departments are not well connected and integrated. Therefore, doctors have limited access to patients' information stored in other departments during their clinical and treatment decision-making process. Tele-medicine solutions remain under a "pilot phase" and the application of Artificial Intelligence (AI) and Big Data in the health sector remains limited.

In general, the challenges for the digital transformation of healthcare can be grouped into three topics:

- *Limited digital compatibilities of healthcare professionals are a barrier to digital adoption:* Hospital IT departments are mainly responsible for operations and management of hardware and software systems, rather than the long-term goal of digital adoption. Besides, there is yet to be strong alignment in terms of digital envisioning between the top management who make decisions on technology investment and the doctors/nurses who are the real users of those technologies. The reluctance of these users to apply new tools may result in the slowdown of digital adoption in hospitals.
- *Financial pressures:* Hospital management software and the broader information technology infrastructure are expensive. While digitalisation has emerged as a key value proposition of private hospitals as they seek to compete with the more established public hospitals by investing heavily in digital platforms and considering digital as an essential factor to attract high-income patients, financial constraints in public hospitals are slowing down the process of digital transformation.
- *Limited data conformity and cybersecurity issues are hindering the integration of systems:* Currently, there are no national standards in place for data output and cybersecurity. Despite the guidance from central Government and local authorities, each organisation has its own standards, thus limiting inter-hospital connections. Data security concerns have led healthcare providers to be reluctant in storing patient information on the cloud and/or sharing their network with outsiders.

Potential gains/concerns for Vietnam

The COVID-19 pandemic provides a strong incentive to accelerate digitalisation in healthcare. Post-pandemic investments in digital technologies for use in customer engagement, care coordination, enabling a remote workforce or telemedicine will be higher once the threat of COVID-19 has waned. Telemedicine, already undergoing rapid growth, has quickly become a key tool for both preliminary COVID-19 screening and also for non-urgent care and consultations.

4 "Sustainability and Resilience in the Vietnamese Health System", Health Strategy and Policy Institute, Vietnam, March 2021. Available at: <www3.weforum.org/docs/WEF_PHSSR_Vietnam_Report.pdf >, last accessed 4 May 2021.

Therefore, healthcare systems must prepare for this tectonic shift now. Many patients are staying away from emergency departments and other healthcare locations, shifting to virtual care services or digital front doors. In addition, patients are increasingly approaching healthcare as consumers and looking for the same fast, easy and affordable service they have come to expect in other areas of life. What patients have found in virtual care is a healthcare model that allows them to consult with providers regardless of where they or the providers are located, and provides them with online tools that allow them to monitor and manage their own care. For the case of healthcare providers, the digital front door is a model which is both flexible and scalable, and allows them to direct their patients towards the care they need, engage with them from any distance, monitor their progress and manage their care.

It is an increasing trend, especially among the younger generations, to use technologies such as websites, smartphone apps, personal medical devices or fitness monitors to measure fitness and health-improvement goals. As Vietnam develops, urban youth are integrating health technology into their lives, driving wearable fitness and activity tracking technology. Indeed, more than two million people in Vietnam now own some form of wearable technology. Health monitoring is the primary reason for Vietnamese consumers to purchase this wearable tech.[5] Regular health check-ups, for many Vietnamese people, require a visit to a local hospital or clinic, which contributes to crowding and additional pressure on already strained healthcare practitioners. Remote patient monitoring solutions from healthcare providers will allow people to communicate with their doctors and track information from the comfort and convenience of their homes. This will free-up bed space, lower the cost for patients, and allow for easier discharge of low-risk patients.

Virtual care is beginning to influence patients' selection of healthcare providers. Increasingly, patients expect digital capabilities and are more likely to choose a healthcare provider who offers prescription refills electronically, reminders via email or text message, email communication, online appointment bookings, as well as tele-monitoring or tele-consultation. Younger patients, in particular, are less satisfied with the traditional ways of accessing healthcare and are more willing to try non-traditional services such as virtual health. Eighty-four per cent of Baby Boomers have a primary care physician. However, amongst members of Generation Z – those born after 1996 – this figure drops to 55 per cent.[6] Moreover, 41 per cent of Generation Z report that they prefer a virtual or digital experience with their healthcare professional. For Baby Boomers, this drops to 9 per cent.[7] Through virtual health technologies, healthcare providers are now able to reach patients almost anywhere. The reverse is equally true: other providers, located almost anywhere, are now able to reach and compete for patients.

Digital front doors allow healthcare providers to engage with patients at every major touchpoint of their healthcare journey. New digital services will improve access to care, optimise clinical operations, and better manage population health, while at the same time increasing workforce productivity. Digital front doors enhance four different areas of provider-patient interaction.

Directing and engaging with patients virtually

5"Digital Health in Vietnam" Market Intelligence Report, KPMG, December 2020. Available at: <https://assets.kpmg/content/dam/kpmg/vn/pdf/publication/2021/digital-health-vietnam-2020-twopage.pdf>, last accessed 29 April 2021.
6 "Today's consumers reveal the future of healthcare" (2019), Accenture Digital Health Consumer Survey 2019.
7Ibid.

Digital front doors can serve as navigation signposts along the patient journey, triaging and directing patients to the appropriate level or type of care while, at the same time, feeding the system with information. Moreover, it is a vital tool that allows care teams to engage with patients virtually.

Patients are potentially able to reach out to care teams virtually through smartphones, tablets or laptops in order to be in contact with healthcare providers when the need arises. Tele-visits allow patients to easily make appointments and make better use of their waiting time before those appointments. They also ensure social distancing – a major issue during COVID-19. These virtual visits also have the potential to deliver care of the quality that patients demand. Another value tele-visit brings to the table for healthcare providers is enabling them to expand access to speciality care in underserved regions where there is a lack of specialists. Finally, these digital front doors represent significant potential cost savings for patients, in the form of reduced travel time and, therefore, fewer travel expenses. For chronically ill patients who consult with their physicians regularly, these savings can be significant.

During a virtual visit, physicians can consult with patients and treat them directly with advice or a prescription or direct them to the appropriate offline healthcare provider. Alternately, chat-bots or other automated tools can collect patient symptoms and data automatically, with AI-powered systems performing intelligent analysis and making recommendations on next steps. Either way, patients are properly directed, which results in better outcomes while also relieving stress on the system caused by unnecessary emergency department visits.

Monitoring patients remotely

Digital front doors allow providers to keep a remote eye on patients' signs and symptoms, identifying when they are at risk and providing them with individualised care management programs. Chronically ill patients can be monitored by healthcare providers regularly and remotely, allowing for early recognition if things start to go wrong and suitable intervention to avoid an emergency.

The data should be provided voluntarily by the patients with the assurance from the medical providers that the data will not be used for commercial purposes. If patients agree to use wearables and other measuring and monitoring devices, providers will have the data they need to provide better care. In addition, the generated data can then be aggregated in an electronic health record. With electronic health records, patients can access their health data and information. This allows them to upload that information and decide upon authorisation rights. It also promotes their active participation in their care process, and allows physicians to access data that has previously been locked away in silos of information systems throughout the healthcare infrastructure.

Monitoring population health

Digital front doors offer flexibility and an opportunity for health systems to better manage overall population health, identifying and responding to trends, and establishing new care delivery models. Furthermore, healthcare providers will be able to analyse and operationalise data received digitally from large patient populations. Healthcare providers can identify vulnerable cohorts and pave the way for proactive, targeted and even virtual engagement, as well as the administration of anticipatory care to avoid disease development and progression.

Any successful healthcare endeavour depends on patients. Digital front doors are no different, and patient buy-in is essential. In the case of older patients, many of whom suffer from chronic diseases, real-time monitoring and easier access to physicians can have a positive impact on unplanned readmissions, quality of life, and mortality. However, as older people are not always comfortable with new technology, a stronger engagement and education effort may be required. In the case of younger patients who are familiar and comfortable with new technologies, this education process will be easier. However, because of the nature of digital care, patients will almost certainly have different options and different providers to choose from.

It is quite possible, in fact, that more comparison websites and portals will emerge, helping patients to navigate what is, in effect, a provider marketplace. Thus, providers will have to turn their attention to digital marketing efforts such as brand management, search-engine optimised marketing, social media engagement, and platforms for patient reviews, in an effort to convince young, digitally-aware patients to choose their digital front doors.

If the first priority in any healthcare undertaking is patients, the second must be the workforce. In the case of digital front doors, existing staff need to be trained to work with the new technology, and should be integrated into the change processes that will be necessary through their workplaces. Existing staff need to be made aware of how new digital options will make their workplace more flexible. This will create incentives and motivation, which are crucial during this change process. In addition, new staff may be required; as a larger part of the infrastructure is going to become digital, a larger proportion of digital experts will be required.

To be usable, digital front doors will need to be integrated into existing infrastructure. That will require investment in new hardware (e.g., smart devices, tablets, etc.), and software. Improved wireless capabilities (e.g., a move to 5G) may also help to provide the needed connectivity. Data storage will pose a challenge for many, with a shift to cloud-based data storage offering a potential solution. The costs for infrastructure and technology upgrades such as these, as well as those related training, could prove to be a barrier for many organisations. Opportunities for flexible funding alternatives or partnership models might help to ease these pressures. Vendors with the relevant experience could be valuable partners during such transitions.

Optimising workflows is an ongoing challenge in all healthcare environments. Depending on the archetype and size of the healthcare provider, workflows will differ and the integration of digital front doors will involve a number of moving parts. Infrastructure, data, workforce and patients will all have to be incorporated. However, digital front doors will benefit from the arrival of new solutions that allow for simulation of workflows. This will result in a dependable prediction of the operational and financial impact before integration occurs, allowing for preparations to be made.

Vietnam is in the early stages of using AI and Big Data in healthcare: Only a few hospitals out of 1,400 currently have any form of AI usage.[8] Currently, there is no legislation specifically governing Big Data and AI health applications, apart from those detailed in the 2019 adoption of Decision 4888/QD-BYT.[9] Issues of security and confidentiality are of increasing concern to all consumers, and especially for medical data which is particularly sensitive. These issues

8 Ibid.

9 Decision 4888/QD-BYT dated 18 October 2019 of the Ministry of Health introducing the Scheme for the application and development of smart healthcare information technology for the 2019-2025 period.

must be addressed in an effective and comprehensive way, not only at the level of individual providers but also at a broader regulatory or legislative level. A properly integrated healthcare system will depend on the ability of providers of all types to share information, and patients must have confidence that their digital data is being treated securely. Internal data security governance capabilities are essential, as well as a thorough understanding of data flows in order to proactively anticipate potential security vulnerabilities.

Recommendations

We would like to make the following recommendations:

- Be prepared for the changed approach of the healthcare market by approaching current and future patients in a different way.
- Train staff to handle the new digital options and hire appropriate new staff where necessary.
- Invest in new hardware and software suitable to provide these new digital services.
- Find alternative flexible funding or partnership models to save costs.
- Optimise workflows using the options the (new) digital environment provides.
- Ensure that patients' data is protected.
- Develop legislation governing Big Data and AI for healthcare applications.

II. MACHINE INSTALLATION MODEL IN HOSPITALS

Relevant authorities: Office of the Government (OOG), Ministry of Health (MOH), Ministry of Finance (MOF), Ministry of Planning and Industry (MPI), Vietnam Social Security (VSS)

Issue description

Along with the increase in investment from the Government and socialisation policy, and due to the Machine Installation model in public hospitals (the Machine Installation model is one where the company who won the bid for chemicals and materials has to place the machines so that the bidder can use them[10]), much modern equipment has been purchased. This creates conditions for the deployment of high-tech in medical examination and treatment as well as better diagnosis, detection, and treatment of diseases.[11] Many high-tech medical technologies in Vietnam have reached the international level. Not only does it serve the Vietnamese people, it also means that the country has become a destination for many overseas Vietnamese patients and those from neighbouring countries. This has put the Vietnamese medical brand on the world map.

The Machine Installation model is applied widely in many countries in the Asia Pacific region such as Singapore, the Philippines, and India[12] as well as in developed countries in the G7.[13]

10 "Many forms of socialization of medical equipment", VTV Online, dated 17 June 2018. Available at :< https://vtv.vn/trong-nuoc/nhieu-hinh-thuc-xa-hoi-hoa-trang-thiet-bi-y-te-20180617113652741.htm>, last accessed on 25 April 2021.

11"Vietnam Health: Continued success, creating a solid foundation for development", The Ministry of Health, dated 2 January 2020. Available at : <https://moh.gov.vn/chuong-trinh-muc-tieu-quoc-gia/-/asset_publisher/7ng11fEWgASC/content/y-te-viet-nam-tiep-noi-thanh-cong-tao-tien-e-vung-chac-e-phat-trien>, last accessed on 25 April 2021.

12 "The changing landscape of the medical devices industry in the APAC region", KPMG, March 2020, page 15 to 16. Available at: <https://assets.kpmg/content/dam/kpmg/jp/pdf/2020/jp-medical-device-apac-en.pdf>, last accessed on 25 April 2021.

13 Global Atlas of medical devices, WHO medical devices technical series, 2017, page 81. Available at: <www.who.int/medical_devices/publications/global_atlas_meddev2017/en/> last accessed on 25 April 2021.

However, public hospitals and enterprises are currently facing difficulties with this model. It has been implemented for many years in Vietnam, but there remain inconsistencies in policies from VSS, MOH, and MOF. This has led to difficulties in Machine Installation and insurance payment for services using installed machines. The issue was also presented in the 2019[14] and 2020[15] editions of the Whitebook and other EuroCham documents in 2020.

The current status can be summarised as follows: In 2018, MOH and VSS had many discussions about the payment of medical examination and treatment expenses for health insurance by the VSS by the machines lent or placed by the company which wins the materials and chemicals bid.

Medical socialisation and the Machine Installation model in public hospitals has been discussed at meetings with leading representatives from MOH, MOF, MPI, OOG and VSS. The unified solutions given by MOH and VSS to remove difficulties for insurance payment for technical services performed on machines lent or placed by chemical contractors at public hospitals are appreciated. These solutions aim to ensure transparency, publicity, and harmonisation of benefits between medical examination and treatment facilities, patients, and the health insurance fund.

Specifically, the solution aligned on by MOH and VSS in Notice 1039/TB-BYT-BHXHVN[16] is, in our view, a good solution. It consists of proceeding payments for medical examination and treatment expenses, subject to health insurance, of the services performed by placed or borrowed machines provided by the winning suppliers, following the bidding result as per the Law on Bidding and signed contracts. After the expiry of the contract, continued installation shall be subject to regulations under Decree 151/2017/ND-CP[17] (Decree 151). However, Decree 151 has not prescribed the forms of lending or installing machines and does not specifically guide the implementation for some forms of socialisation such as leasing.

Potential gains/concerns for Vietnam

The machine installation model has advantages that have been recognised by MOH and health facilities.

Firstly, it contributes to reducing State budget expenditure. In specific circumstances, such as COVID-19, the demand for equipment for testing, diagnosis and treatment of medical examination and treatment facilities has become significant[18], while the State budget and legal sources for investment are limited. If the model is not applied, the State or health facilities will have to invest trillions of dong to buy testing machines. Therefore, the Machine Installation model is one of the necessary solutions for medical facilities to have equipment and for people to enjoy high-quality medical services.

Secondly, material and chemical prices are transparent in compliance with the law, bidding process and results. There is no difference in the price of materials or chemicals purchased for the machine installation model, purchased machine or socialised machine.

14 WhiteBook 2019, EuroCham.
15 WhiteBook 2020, EuroCham.
16 Notice 1039/TB-BYT-BHXHVN dated 2 October 2018 of the Ministry of Health on the conclusion of Deputy Minister of Health Pham Le Tuan and Deputy General Director of Vietnam Social Security Pham Luong Son at the Briefing Conference of Two branches.
17 Decree 151/2017/ND-CP dated 26 December 2017 of the Government on management and use of public assets.
18 “Enterprises of pharmaceutical materials and medical equipment overcome COVID-19”, Lao Dong, dated 21 August 2020. Available at: <https://laodong.vn/kinh-te/cac-doanh-nghiep-duoc-vat-tu-thiet-bi-y-te-vuot-tro-ngai-covid-19-829706.ldo>, last accessed on 25 April 2021.

Thirdly, VSS pays the technical services under the applicable insurance price bracket and the application is the same, regardless of whether the service is performed on the installed machine, the purchased machine, or the joint venture.

In Vietnam, inconsistencies in documents guiding implementation for medical facilities and stakeholders has caused challenges for companies and health establishments when choosing the appropriate model for new machines. We are concerned that this will interrupt the implementation of diagnostic and therapeutic tests for patients, especially fast, critical tests. At the same time, the risks faced by hospitals are that they will lose opportunities to receive advanced and modern laboratory techniques that have been applied in advanced countries, and the financial burden for the State and hospitals will increase if they have to invest in and purchase machines. On the business side, this makes it difficult to handle and maintain the machines that were previously placed in the hospital, as well as the new machines to be located in the hospital.

We understand that authorities are reviewing the regulations relating to the Machine Installation model in order to have appropriate amendments in the future, including: issuing an official letter guiding the payment of health insurance which, hopefully, will result in the relevant Decree being amended.

Recommendations

We would like to make the following recommendations:

- Add the machine installation model to the official documents of consistent policy from relevant Ministries (MOH, MOF, and VSS) regarding the model of placing equipment in public health establishments, to create an open and transparent legal framework.
- Continue and approve insurance payment for technical services performed on placed machines until the new regulations to amend and supplement the machine installation model have been issued.
- Circulate the documents and provide training for relevant stakeholders to allow a better understanding of the policy as well as full compliance with the law.

ACKNOWLEDGEMENT

EuroCham’s Medical Devices and Diagnostics Sector Committee.