A Regulatory Perspective of Digital Health Transformation: A Singapore Case Study

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Preface

The National University of Singapore (NUS) Initiative to Improve Health in Asia (NIHA) was established in 2010 with funding support from the Singapore Economic Development Board (EDB) and GlaxoSmithKline. This initiative aims to progress public health and healthcare delivery in Asia through three approaches:

1. **Leadership programme.** To equip healthcare leaders across the region with important leadership competencies to tackle relevant healthcare issues, and drive health and healthcare innovation in the region.
2. **Research.** To develop innovative solutions to the pressing healthcare challenges facing the region and to promote evidence-based health policy.
3. **Policy forums.** To foster dialogues and partnerships among policy makers, non-governmental organisations, academia, and the private sector on the opportunities and challenges of healthcare in the region.

This paper is a culmination of the presentations and discussions that took place in the NIHA policy forum held on 21 July 2023. The NIHA forum brought together experts from government, academia, the healthcare sector, and industry to address the question, "Are we ready for a Digital Health Future?", focusing on the readiness of Asia-Pacific health systems, governments, and populations to embrace the opportunities and challenges of digital health. The theme of the forum was, "Transforming Healthcare for the Next Decade" and the discussions revolved around digital transformation in the healthcare sector, the challenges and opportunities, digital health policies and regulations and the road ahead with AI in healthcare.

The sessions on digital transformation in the healthcare sector provided insights into Singapore's healthcare digital transformation journey, the risks and opportunities of AI in healthcare, the digital healthcare start-up scenarios and culminated in a panel discussion highlighting the need for collaboration, innovation and transparency in the digital health landscape while addressing the issues of digital health equity, access and trustworthiness of AI in driving digitalisation of the healthcare sector.

The sessions on digital health policies and regulation covered the aspects of facilitative regulatory frameworks in the context of the transforming healthcare sector. Speakers shared their perspective on the significance of digital health regulations and the challenges around the pace and novelty of digitalisation of healthcare sector brought in by generative AI. The

panel discussion focused on the theme of regulation of AI in healthcare and its potential impact on innovation. The discussion highlighted the importance of balancing innovation with patient safety while making regulations adaptable to the changing scenario.

Influenced by the dilemmas that surfaced during the forum this paper will clarify the concept of digitalisation of healthcare sector, describe the key components of the digital transformation journey of Singapore, discuss the digital health regulatory framework in Singapore and provide recommendations for addressing the identified regulatory challenges.

Executive Summary

Introduction. As the healthcare sector undergoes a remarkable digital transformation it is becoming more interconnected, and data-driven. The digitalisation of healthcare balances innovations on one hand and risks and challenges on another. Digital health solutions are addressing the issues encountered by the traditional healthcare model, known for its reliance on paper-based records, fragmented communication, and limited availability of timely information. The digitalisation of healthcare encompasses seamless data exchange and application of Artificial Intelligence (AI) and Machine Learning (ML) to enhance clinical decision-making and remote consultations that make healthcare more accessible. The transformative impact of digitalisation has been observed in healthcare administration as well as diagnostic, treatment, and research. Regardless of the transformative impact of digitalisation, there are existing and anticipated risks related to data privacy, ethics and patient safety that policymakers are addressing globally.

Methodology. The NIHA policy forum explored the digital transformation in the healthcare sector and the regulatory pathways required to respond to the changing landscape. This paper consolidates the insights from the forum speakers as well as a review of the literature to help regulators and healthcare leaders as they develop strategies to support innovations in a safe and ethical manner. It examines the key components of the digitalisation of healthcare services, discusses the digitalisation of healthcare services in Singapore, identifies regulatory challenges, describes the existing digital health regulatory frameworks across the world and provides recommendations for making the digital health services safer and ethical.

Findings and Recommendations. The results show that digitalisation of the healthcare sector has spawned a wide range of applications to modernise, optimise and personalise healthcare services. Singapore's journey of digitalisation has been charted by a robust data management system and AI led innovations. Challenges requiring regulatory attention have been well documented and include data privacy, security, trustworthiness of AI and the difficulties in wide-scale implementation of novel therapies based on genetic technology. The human and cultural factors also need to be considered while policy-makers plan for large-scale digital transformations as such factors may impede acceptance of the transformation. In terms of regulation of such a dynamic environment, Singapore has adopted a risk-based approach employing regulatory sandboxes that help create guidelines and regulations when required. Globally, the regulation of digital health technology is still evolving, especially with respect to AI and novel therapies. Recommendations indicate a need for regulations that are

tailored to the requirements of digital health technologies, that are specific to digital products and services based on such products, data protection privacy and intellectual property rights.

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1. Introduction

1.1. Journey of digital healthcare

It is an understatement that, in recent years, the landscape of healthcare has undergone a remarkable transformation, driven by the rapid advancement of digital technologies. As the world becomes increasingly interconnected and reliant on data-driven solutions, the healthcare sector is embracing a new era. This paradigm shift, often referred to as the "digitalization of healthcare," encompasses a wide range of innovations and strategies that leverage digital tools to enhance patient care, improve operational efficiency, and redefine the way healthcare services are delivered. The traditional healthcare model, known for its reliance on paper-based records, fragmented communication, and limited availability of timely information, has consistently encountered significant obstacles.

These challenges include rising healthcare costs, inefficiencies in care coordination, disparity in access to quality healthcare services, and the need for more accurate and personalized treatment options. In response, healthcare providers, researchers, and policymakers are turning to digital technologies to address these issues and unlock new possibilities for the healthcare industry.

At the heart of the digitalisation of healthcare lies the concept of seamless data exchange and integration. Electronic Health Records (EHRs) have emerged as a cornerstone of this transformation, enabling healthcare professionals to access comprehensive patient information securely and instantaneously. This not only enhances clinical decision-making but also supports more effective communication and collaboration among multidisciplinary care teams. Telemedicine has further accelerated the digitalisation process, offering a means to bridge geographical gaps and extend medical expertise beyond the confines of traditional healthcare facilities. Patients can now engage in remote consultations, receive timely medical advice, and monitor their health conditions through mobile apps and wearable devices, ushering in an era of patient-centric care.

Furthermore, the application of Artificial Intelligence (AI) and Machine Learning (ML) holds immense promise in revolutionizing diagnostics, treatment, and research. AI algorithms can analyze big datasets to identify patterns, trends, predict disease outcomes, and assist healthcare providers in making more accurate diagnoses and thereby effective treatment. Integration of AI also opens avenues for personalized therapies tailored to an individual's

genetic makeup and medical history. However, as the healthcare industry embarks on this digital transformation journey, it also grapples with complex challenges. Data security and privacy concerns are paramount, as the digitalisation of healthcare necessitates secure storage and sharing of sensitive patient information. Interoperability issues, where different digital systems struggle to communicate effectively with one another, pose additional obstacles to seamless data exchange and collaboration amongst healthcare providers.

In this context, the digitalisation of healthcare presents a tremendous opportunity to reshape the way healthcare is delivered, experienced, and managed. This comprehensive integration of digital technologies has the potential to break down barriers, drive innovation, and ultimately lead to better patient outcomes, improved population health, and a more efficient and responsive healthcare ecosystem. As we delve deeper into the digitalisation of healthcare, it becomes evident that the convergence of technology and medicine is not just a trend but a fundamental shift with the potential to redefine the future of healthcare as we know it.

1.2. Digitisation vs Digitalisation

Before we dig deep into digital health, it is paramount to understand the difference between digitalisation and digitisation as the two terms are often used interchangeably, but they have distinct meanings, especially in the context of healthcare (Vrana and Singh, 2021; Gradillas and Thomas, 2023).

Digitisation. Digitisation refers to the process of converting information, data, or content from analog or physical formats into digital formats. In the healthcare context, digitisation involves the conversion of patient medical records, images, documents, and other relevant information from paper or film-based formats into digital files. This process aims to create electronic versions of physical information, making it easier to store, access, and share electronically. Digitisation helps in reducing paper-based processes, improving data accuracy, and enabling more efficient data management and transfer.

Digitalisation. Digitalisation goes beyond the mere conversion of analog information to digital formats. It involves using digital technologies to transform and optimize processes, workflows, and practices within an industry or organization. In healthcare, digitalisation refers to the integration and use of digital technologies such as (EHRs), telemedicine platforms, mobile health apps, wearable devices, data analytics, and artificial intelligence to improve patient care, streamline administrative tasks, enhance decision-making, and enable new healthcare

delivery models. Digitalisation aims to leverage the capabilities of digital technologies to bring about both fundamental and structural changes in how healthcare is delivered and managed. In summary, digitisation is about converting analog information into digital formats, while digitalisation involves using digital technologies to transform and improve processes and practices. In healthcare, digitisation might involve scanning paper medical records to create digital copies, while digitalisation could encompass implementing EHR systems, telemedicine platforms, and AI-powered diagnostics to revolutionize patient care and healthcare management.

2. Digital Health – Application Areas

Digital health refers to the integration of digital technologies into all aspects of the healthcare industry to improve patient care, enhance operational efficiency, and enable new ways of delivering healthcare services. This transformation encompasses a wide range of technologies, strategies, and processes aimed at modernizing and optimizing the healthcare sector. Here are some applications and areas through which digital transformation of healthcare has been profound (Abernethy, et al. 2022; Gunasekeran, Tseng, Tham and Wong, 2021):

1. EHR: The adoption of electronic health records allows healthcare providers to store, manage, and access patient information electronically, leading to better data accuracy, improved communication, and streamlined workflows.

2. Telemedicine and Telehealth: Telemedicine involves the use of digital communication technologies to provide remote medical consultations, diagnoses, and treatment plans. It enhances access to healthcare services, particularly in remote areas and during emergencies.

3. Mobile Health (mHealth): Mobile applications and devices have revolutionized healthcare by enabling patients to monitor their health, access medical information, and even receive treatment guidance through their smartphones and wearable devices.

4. Health Analytics and Big Data: The collection and analysis of vast volumes of healthcare data can lead to insights that improve patient outcomes, resource allocation, and disease prevention. Predictive analytics can identify trends and patterns for better decision-making.

5. Internet of Things (IoT) in Healthcare: IoT devices, such as wearable sensors and remote monitoring devices, enable continuous patient data collection and real-time monitoring. This aids in early detection of health issues and timely interventions.

6. Artificial Intelligence (AI) and Machine Learning (ML): AI and ML technologies are being used for tasks like medical image analysis, diagnosis, drug discovery, and personalized treatment recommendations. These technologies improve accuracy and speed up processes.

7. Virtual Reality (VR) and Augmented Reality (AR): VR and AR are being applied in medical training, patient education, and surgical simulations, enabling healthcare professionals to practice and acquire skills in lifelike virtual settings.

8. Blockchain in Healthcare: Blockchain technology enhances security, privacy, and interoperability of healthcare data, making it useful for secure patient data exchange, supply chain management, and insurance claims processing.

9. Remote Patient Monitoring: Devices and applications that allow continuous monitoring of patients' vital signs and health metrics from their homes, enable early detection of changes in health status, and reduce hospital readmissions.

10. Personalized Medicine: Digital tools, such as genetic testing and molecular profiling, enable tailoring treatments to individual patient's genetic makeup and health characteristics for more effective and targeted care.

11. Health Information Exchange (HIE): Digital platforms that facilitate the secure exchange of patient health information among healthcare providers improve care coordination and reduce duplicated tests or procedures.

The digital revolution in healthcare offers a plethora of advantages, such as enhanced patient results, cost efficiencies, increased patient involvement, and streamlined healthcare delivery. Nevertheless, it also poses obstacles concerning data security, compatibility, and the necessity for healthcare practitioners to embrace novel technologies and processes. Based on this premise, this document has been composed to deliver a thorough viewpoint on the digital transformation of healthcare, digital health regulations, and strategic counsel from a regulatory standpoint, focusing on the context of Singapore.

3. Digital transformation in the healthcare sector

The digital transformation of the healthcare sector received an impetus during the pandemic in 2020. The pace at which the healthcare sector turned to digital solutions was driven by the need to deliver services in an environment requiring remote healthcare delivery due to safe distancing measures and lack of hospital space and personnel. Health tech innovators were critical in this response and have continued to boost the digital transformation journey of the healthcare industry. Gopal, Suter-Crazzolara, Toldo and Eberhardt (2018) recognise that

digitalisation of healthcare can occur at differing speed depending on the "location, size and strategy of the organisation". Digitalisation is an evolving transformation starting from simple digitisation of paper-based record to actual digitalisation that operates on higher order analytics using Machine Learning (ML)/Artificial Intelligence (AI). Digital transformation of healthcare will ultimately aim for better care, stronger organisations, and integrated ecosystems. This is therefore a very complex process and requires a strong policy, funding and large-scale data integration and adoption of interoperable technology solutions.

Singapore's digital transformation journey has reached a pivotal moment with the introduction of its Healthier SG strategy in July 2023. This section will begin with a discussion of the policy and its impact on digitalisation, describe the information technology system to support the transformation, and systems to drive healthcare innovation, discuss challenges of digitalisation and look at what the future of digitalisation of healthcare in Singapore looks like.

3.1. Impact of Healthier SG strategy on digitalisation of healthcare in Singapore

A rapidly ageing population and increasing disease burden have triggered a paradigm shift from curative care to preventive care in Singapore (MOH, 2022c). The Healthier SG strategy aims to transform hospital-based care to community-based care, made possible through a strong digital transformation of the healthcare sector. Healthier SG has five key components:
1. mobilise family doctors to deliver preventive care for residents;
2. develop health plans that include lifestyle adjustments, regular health screening and appropriate vaccinations which doctors will discuss with residents;
3. activate community partners to support residents in leading healthier lifestyles;
4. launch a national enrolment exercise for residents to commit to seeing one family doctor and adopting a health plan;
5. set up necessary enablers such as IT, manpower development plan and financing policy to make Healthier SG work.

The two digital front doors for the implementation of Healthier SG are the HealthHub App and the Healthy 356 App. Through the HealthHub App, residents will be linked to their preferred clinic and their family doctor. This app is a powerful digital tool that among other things, helps residents manage their appointments, view their health records, and also manage the health of close others as caregivers. The next step after enrolment is the development of the individual health plan with the family doctor. This health plan will be available on the HealthHub

App helping residents understand their overall health status and in taking actionable steps towards their health goals as planned.

The Healthy 365 App, by the Health Promotion Board (HPB) Singapore, is a necessary companion tool that will help in managing lifestyle choices to achieve the goals set in the health plan. The Healthy 365 app can track daily physical activity, sleep duration and calorie intake. It is linked to various national challenges (National Steps Challenge, Eat, Drink, Shop Healthy Challenge), wellness programmes (Live Well, Age Well programme) and healthy activities such as free exercise classes and health workshops. Importantly, this app incentivises healthy lifestyle choices using gamification methods and is made interoperable with other digital health apps on wearable devices to encourage and nudge residents towards healthier lifestyles.

Apart from the apps tracking medical records and lifestyle records, Healthier SG will be significantly supported by telemedicine. According to the National Telemedicine Guidelines for Singapore, Telemedicine or telehealth refers to providing healthcare services over physically separate environments via information and communication technology (ICT) in which information is exchanged between providers and patients or caregivers. Singapore was able to establish telemedicine systems for those recovering from COVID-19 at home which has increased its acceptability in the community (Blackbox Research, 2022). More larger scale use of telemedicine will ease the pressure on the healthcare delivery systems and will benefit patients with mobility issues. It will also expand the capacity of primary care providers to manage patients with chronic conditions in a cost-effective manner. The delivery of medication directly to the patient's home is also another advantage of the telemedicine system that will help manage chronic illnesses in the community.

Supporting the ambitious implementation of Healthier SG is a strong IT infrastructure that will be the bedrock of an integrated healthcare ecosystem as discussed next.

3.2. Information technology infrastructure to manage the flow of health data

In 2008, MOH set up the Integrated Health Information System (IHiS) later rebranded as Synapxe in 2023, by bringing together the IT teams across the public healthcare system under one organisation. The aim of IHiS/Synapxe was to improve interoperability and data integration and enhance efficiencies in IT operations. It is the national healthtech agency that

partners and supports the Ministry of Health in realising the national healthcare policies and outcomes. IHiS/Synapxe now supports the operation of 46 public healthcare institutions as well as 1,400 partners in the community.

This system has played a key role in accelerating Singapore's digitalisation journey and supported the COVID-19 response. As an example, IHiS was able to set up the COVID-19 Test Repository that brought the swab results from 31 labs into one central location. This was significant as it helped in identifying the infection clusters, triggered contact tracing and quarantine operations in a time efficient manner. Further, IHiS/Synapxe was able to develop systems to enable individuals to monitor their own vital signs when the virus spread in the community. The system was able to deliver and integrate various IT systems to ensure that vaccinations were administered safely and efficiently across multiple centres. The IHiS/Synapxe is a critical part of Singapore's healthcare digitalisation process as it supports care delivery, making large-scale operations possible, enabling seamless and integrated care by connecting healthcare providers, storing, and analysing data and helping individuals monitor their own health (MOH, 2023a). it acts as a 'connector' that enables the flow of information within the health ecosystem.

This centralised agency manages five critical digital systems: the National Electronic Health Record (NEHR), HealthHub App, Next Generation Electronic Medical Records (NGEMR), National Harmonised Integrated Pharmacy System (NHIPS) and the National Billing System (NBS).

The National Electronic Health Record (NEHR) system is a centralised repository of health information established in 2011. It captures the summaries of patients' medical records in a central platform and is accessible by licensed healthcare providers (MOH, 2022a). As such it is enabled to collect and share summarised medical data among healthcare providers such as family doctors, hospitals, and community care partners such as nursing homes to maintain a unified health record for each person. The health information captured by NEHR is extracted from institutions' Electronic Medical Records (EMR) system, and while it does not transfer all patient data, it summarises key health information selected by the MOH. The HealthHub App is a one-stop digital health platform with information on medical conditions and secure access to health records. Patients can access summaries of their key health information through HealthHub App. Apart from NEHR and the HealthHub App, Singapore public healthcare sector has introduced three major programmes to transform care delivery which are:

1. The NGEMR is a single unified electronic medical record across the National University Health Systems (NUHS) and National Healthcare Group (NHG).

2. The NHIPS aims to harmonise medication dispensing and streamline medication-related billing processes. It will be integrated with over 20 systems including NGEMR and the National Billing System (NBS).

3. The NBS will deliver a consistent national billing system across more than 60 public healthcare institutions that will streamline billing processes and enable quicker and easier implementation of the new or revised government policies across healthcare institutions in Singapore.

3.3. Systems to drive healthcare innovation – AI and Genomics

Singapore aims to harness the breakthroughs in medical science technology to ultimately improve the patient care experience. IHiS/Synapxe has been working on creating AI solutions and systems to improve healthcare by early detection and prevention, as well as targeted interventions for people with special care needs. It has also built AI systems for resource optimisation and administrative support (Ta, et al., 2022). There are several examples of AI enabled systems already in use or in development stages in the public healthcare system of Singapore. Targeting early detection and prevention using AI, the Singapore Eye LEsioN Analyser SELENA+ system helps detect three types of eye diseases: diabetic retinopathy, glaucoma and age-related macular degeneration (AMD) by analysing eye retina images (Ta, et al., 2022). Another example of early detection is the AI Engine codeveloped by IHiS and Changi General Hospital, that can accurately predict the likelihood of a patient having mild or severe pneumonia based on their chest X-ray image (MOH, 2023b). AI has also been deployed for the prediction of hospital inpatients with a high risk of multiple readmissions, thereby identifying patients with the most complex care needs, to implement community health and social support after the patient has been discharged. While AI is helping save time and improve predictions using health data, another field that is on Singapore's horizon of digital transformation is the convergence of digital technology and bioscience to unleash the power of genomics. The power of digital technology in vaccine development using genomic data is being used to develop mRNA vaccines and for future pandemic preparedness (MOH, 2022a).

The SG100K research programme aims to collect detailed baseline health information, sequencing and analysing whole genomes of 100,000 Singaporean across different backgrounds and ethnicities to identify myriad factors associated with diseases prevalent in the Asian context. The aim is to better predict and prevent chronic disease and provide value-based and effective healthcare (MOH, 2023c). Innovations and solutions derived from digital technology seem to be moving towards a future in which individuals will be able to receive

treatment that is tailored to their unique genetic makeup and environmental factors. Digital healthcare will improve the primary prevention of diseases in the community by precision prediction of disease onset. In this way, hospital care facilities can be used specifically for acute and complex cases while chronic or simpler cases can be managed in the community through appropriate digital tools.

While the future looks very promising there are pertinent issues that policy makers are grappling with and trying to keep pace with technological advances is always a challenge for regulations. The next section discusses the issues and challenges that will require appropriate oversight mechanisms that will be discussed at the end.

3.4. Challenges in the digital transformation pathways

While the future is exciting and technological advances are occurring at a rapid pace, a set of dilemmas and challenges will emerge together with innovations and breakthroughs. Data privacy and security is probably the most ubiquitous issue. The system's ability to maintain the privacy of the patient's data while adhering to the needs of a more integrated system that requires data portability will need to be addressed. Currently, data encryption and access control are two broad methods of addressing this issue and hence, cybersecurity measures are therefore a necessity in a digital transformation journey. Singapore has taken the step to assist healthcare providers in enhancing their cybersecurity abilities by launching the Healthcare Cybersecurity Essentials (HCSE) in 2021. This document provides guidelines on basic cybersecurity measures that can be adopted to ensure the security and integrity of IT assets, systems and patient data.

Connected medical devices present another security issue. The Internet of Medical Things (IoMT) refers to the network of internet connected medical devices, hardware infrastructures, and software applications used to connect healthcare information technology. The connection of devices to the internet exposes to pervasive cyber risk that can be extremely damaging. Patient safety is at risk of cyber-attacks that could as an example alter dosages on insulin pumps or result in pacemaker malfunctioning. Such attacks can bring down the whole system that is connected through a network.

The other often discussed barrier is the risk associated with application of AI in healthcare. The issue of trustworthiness of AI has been raised because AI algorithm models are dependent on medical data, which are primarily unstructured and lacking uniform and standardised annotation (Zhang and Zhang, 2023). The variability of data quality may cause

algorithmic bias and can affect the predictions and health disparities. Moreover, the issue of opacity of how algorithms come up with an output in generative AI adds on to the lack of trust. This becomes pertinent when it comes to responsibility attribution in AI assisted procedures. Several questions that remain unanswered – for example, who is to be blamed if the doctor accepts a wrong diagnosis or treatment recommendation, the AI or the clinician? Or, how much control will humans actually have over AI decision making?

The field of precision medicine is rapidly evolving with development of novel therapies. While there is excitement for the potential of uncovering the "power of genes" in healthcare, its risks need to be addressed. A systematic review of 92 studies showed several commonly perceived risks among professionals and patients. Genetic tests are usually restricted to selected number of genes and there is lack of evidence for accuracy of the test or the efficacy of treatments Erdmann, Rehmann-Sutter and Bozzaro, 2021), Further, the issue of data privacy and informed consent are problematic due to limited knowledge of patients. This is because patients may not be able to truly understand the terms of reference and consent conditions with respect to genetic data. They may consent to sharing of their genetic data that some private companies may exploit by monetising or selling such data. Similarly, misuse of genetic data by insurance companies and employers of can lead to discrimination and stigmatisation. The cost and sophistication often associated with precision medicine can introduce another caveat, and rendering it unaffordable and potential leading health disparity especially for underprivileged and ethnic minority populations. Lastly, the constant emphasis on data and the perceived responsibility to take control of health may place patients under pressure to constantly optimise their health and may burden the health system with increased need for unnecessary doctor's consultation to discuss test outcomes.

Another issue with the digital transformation of healthcare is the complex interrelationship between human and cultural factors. The pace and acceptance of digital transformation by the users may be out of sync. This is true for both, patients as well as professionals. There is resistance to utilise available digital solutions, for example telemedicine, because of lack of trust, high costs of digital adoption and/or resistance to change or inertia. A study of attitudes and perceptions of general practitioners (GP) in Singapore towards NEHR showed that those in solo practice as compared to group practice and above 40 years of age were less likely to share data onto NEHR (Yong, 2019). The reasons cited by the author are lack of financial resources, knowledge of available financial subsidies or lack of computer literacy. It appears that the NEHR has yet to be accepted by the private ambulatory care institutions. By the end of 2022, only 30% private ambulatory care institutions (such as GPs, specialists, dentists and renal care providers) could view the data. Out of these 30%, only 12% were contributing data

(MOH, 2023d). Thus, even with the infrastructure, the successful transition into a truly digitalised healthcare system will require constant engagement with the professionals and public. Transition phases are always problematic and time consuming, similarly in digital transformation where differences in knowledge, perception and attitude of the patients and professionals will impact the adoption rate.

Finally, the pace of digitalisation of the healthcare sector has resulted in regulatory gaps as countries are developing their governance frameworks. While regulations are urgently needed for aspects of digitalisation with maximum risk to human life and disruption of public healthcare system, it is also important not to overregulate and stifle innovations. The next section will discuss existing regulations and frameworks to address the risks in digitalisation of the healthcare sector.

4. Digital Health Policies and Regulations: Singapore context

Digitalisation begins with simple digitisation of paper-based records to digital versions potentially dissolving data silos, streamlining workflows through seamless data exchange and integration and accelerating growth. With increasing digitisation, the need to safeguard the privacy and security of such integrated data also increases. Singapore takes a layered and coordinated approach when it comes to healthcare regulation – there are wider legislations such as the Penal Code and Personal Data Protection Act that are applicable to Singapore; legislations such as the Health Products Act that are applicable to the various health products and devices; various legislations such as Medical Registration Act, Ethical Code and Ethical Guidelines that are applicable to the various healthcare professionals and finally the Private Hospitals and Medical Clinics Act (PHMCA) moving towards the Healthcare Services Act (HCSA) for regulating the healthcare services. Not only that, Singapore also employs a range of tools such as stakeholder education, guidelines / standards, industry self-regulation modes, regulatory sandboxes, accreditation and regulations / legislations to address the various healthcare regulatory issues. The appropriate regulatory tools are identified for each case to improve the regulatory outcomes while at the same time enabling innovation and healthcare digitalisation. This process is also constantly revisited and reviewed at periodic intervals. Within such a dynamic regulatory landscape, Singapore's digital health regulations have certain provisions to address the issues identified above which will be discussed next.

4.1. Regulations for data privacy and security

As explained earlier, the NEHR system has been established to bring together the patients' medical records in a centralised platform for easy access by licensed healthcare providers and healthcare professionals. As we move towards the concept of Healthier SG, the Ministry of Health, Singapore has formulated the Health Information Bill (HIB) which will be tabled in the second half of 2023 – this Bill is expected to mandate licensed healthcare providers to contribute a copy of selected health information such as demographics, diagnosis, operating theatre notes / procedures / treatments, discharge summary, medications and laboratory reports to the NEHR (MOH, Singapore, 2023a). Singapore is also aiming to link the various healthcare providers such as preventive care sectors, private primary care sectors, public healthcare institutions and intermediate and long-term care sectors with the healthcare administrators and policy makers to facilitate data exchange (MOH, Singapore, 2023a) (reference).

The HIB would also ensure the proper collection, use and sharing of patient information across the different healthcare providers and care settings in a safe and secure manner. This would be done by mandating data governance and cybersecurity requirements for healthcare providers and third-party data intermediaries. In August 2021, the Singapore MOH developed and issued the Healthcare Cybersecurity Essentials (HCSE) to guide healthcare providers on basic cybersecurity measures and ensure the security, confidentiality, integrity and availability of IT assets, systems, and patient data. A dedicated website that covers areas such as common cyber threats, common signs of a cyber-attack, how to respond to an attack as well as available cybersecurity-related resources was also set up. The HIB would stipulate cybersecurity requirements and data governance measures for IT systems and medical devices for healthcare providers and data intermediaries to meet. The cybersecurity requirements that is built on the HCSE would include maintenance of an updated inventory of all IT and data assets; protection and security of IT systems and services via anti-malware, differential access controls and secure configurations; regular backups of essential systems and data; development and putting into practice policies and processes for outsourcing, incident response and management and staff awareness and training; and regular updating of software and security patches (MOH, 2023b). The data governance measures that are aligned with the Personal Data Protection Act (PDPA) standards would include data security classification, user access safeguards, storage, conveyance, transmission and disposal requirements, security review and audit requirements.

4.2. Regulation of evolving technologies in healthcare

The fast-evolving and complex digital healthcare landscape presents new challenges for regulators and it is important for regulators to strike the right balance between regulations and patient safety while facilitating the innovation of digital health services. Singapore uses a risk-based approach to the regulation of new services. Prior to adoption of telemedicine, MOH used a regulatory sandbox between 2018 and 2021 in which 11 private providers, namely, WhiteCoat, MyDoc, DoctorAnywhere, HiDoc, DoctorWorld (Raffles Medical), MaNaDr, Sata Health, Parkway, MHC, Speedoc and Rescu participated. The main objectives of the sandbox were to better understand the risks of telemedicine, encourage the safe growth of the telemedicine healthcare service and to co-create regulations with stakeholders. In February 2021, the sandbox transited to the voluntary listing of direct telemedicine service providers, which includes approximately 900 to-date. The lessons from the sandbox were distilled into free e-training modules for healthcare professionals to enable the safe use of telemedicine. The sandbox also prepared providers for licensing under HCSA. Currently direct doctor and/or dentist led teleconsultations are licensable under the HCSA. This includes provision of medical services via technological means (telephone, internet-based video, email and other similar electronic based communications) where the doctor and patient are not physically in the same location is regulated under HCSA. Other telemedicine services such as telecollaboration and telesupport for administrative purposes are not licensed under HCSA. Thus, companies that only operate the telemedicine platform or provide software services are not included under HCSA. Specific guidelines are present in the National Telemedicine Guidelines for Singapore, published in 2015 and developed in collaboration with telemedicine practitioners with representation from relevant medical associations, professional bodies and professionals from different sectors and healthcare settings. International experts were also involved in the development of these guidelines. The guidelines include principles to address patient and provider safety and include mandatory requirements alongside requirements that are strongly encouraged and truly optional (MOH, 2015). Other codes that apply to the practice of telemedicine include Singapore Medical Council's Ethical Code and Ethical Guidelines and Handbook on Medical Ethics; Regulatory Guidelines for Telehealth Products by Health Sciences Authorities; Health Products (Licensing of Retail Pharmacies) Regulations and Telepharmacy Guidelines; and Singapore Dental Council's Ethical Code and Ethical Guidelines (DLA Piper, n.d.).

The Private Hospitals and Medical Clinics Act 1980 (PHMCA) is also slowly transitioning to HCSA to allow the flexibility to accommodate the changes in the evolving healthcare landscape. Under the PHMCA, fixed premises such as hospitals, nursing homes, medical

clinics and clinical laboratories were regulated under premises-based licensure. This is now moving towards services-based licences to accommodate new models of care such as emergency ambulance services, outpatient medical services, assisted reproductive services and clinical laboratory services. This would enable patient safety regardless of delivery mode and there is also the scope for broadening this regulatory regime if required.

The next major subset of digital health that is traversing across the entire healthcare system is Artificial Intelligence (AI), which is being applied from early detection and triaging of patients all the way to diagnosis, treatment and monitoring of outcomes. AI Medical Devices (AI-MDs) are regulated by Singapore's Health Sciences Authority (HSA).

To support patient safety and improve trust in the use of AI in healthcare, MOH, HSA and IHiS co-developed the MOH Artificial Intelligence in Healthcare Guidelines (AIHGle – read as agile) (MOH, 2022b). The two main purposes of AIHGle are to share good practices with AI developers and AI implementers (institutions where it is implemented) and complement HSA's regulations on AI-MDs. However, the guidelines focus on the algorithms that provide the same result each time the same input is applied to it. It may be necessary to factor in the advent of generative AI which can change the outputs over time as it comes across new data. Early guidance is provided for such AI algorithms. Overall, the guidelines focus on higher risk medical and clinical use of AI. The AIHGle provides recommendations for developers and implementers to ensure basic safety for AI in clinical healthcare settings. These recommendations are based on the key principles of fairness, responsibility, transparency, explainability and patient-centricity. The basic concern of AIHGle is all those activities that have a direct impact on patient safety including treatment, patient monitoring and diagnosis and screening (*MOH, HSA & IHiS, 2021*). Similar to telemedicine, AI regulations exist in the intersections of various other existing regulations and guidelines. The AIHGle document lists 12 other relevant legislations and guidelines that need to be considered by organisations or individuals involved in development and implementation of AI-MD (MOH, HSA & IHiS, 2021).

The challenge of finding a right balance to avoid under or over regulation of digital health is common across countries that are experiencing and embracing digital transformations in the healthcare sector. Regulation of healthcare services undergoing digital transformation is very complex because there is no one size that will fit all and the oversight mechanisms traverse various regulations and guidelines. The questions that developers, implementers, patients and policy makers are grappling with include the issue of making AI more explainable, addressing the issue of cross-border application of telemedicine, the variation in regulatory requirements of each country and the increasingly blurred lines between health product and health services

due to digitalisation. Based on these discussions the following recommendations can be considered to tackle some of the regulatory issues with respect to digital health.

5. Recommendations for regulation of digital health in Singapore

Amalgamating and analysing existing regulatory frameworks for digital health, the recommendations provide a way forward for Singapore and can be useful for other economies dealing with the common challenge of regulating or rather calibrating the regulation of digital health. A comprehensive digital health regulatory framework needs to include the following key components:

1. General healthcare regulations that are relevant to digital health
2. General digital health technology regulations
3. Digital tools specific regulations
4. Data protection and privacy
5. Intellectual property

The general healthcare regulations that are relevant to digital health would include the existing legislations such as consumer protection laws, licensing requirements, medical device approval regulations, electronic system laws and cross-border healthcare services. However, they would need to incorporate the aspects of digital health solutions.

Some well-established examples come from Germany, United States and Europe. The Civil Code of Germany and The Federal Trade Commission Act of the United States clearly define corporate and individual liabilities that also encompasses digital health solution liabilities. Europe's General Data Protection Regulation (GDPR) defines a framework for cross-border data sharing, storage, usage along with liability clauses for health data. Certain APAC economies such as Singapore and the Philippines have robust regulations for consumer protection including defining liabilities with robust frameworks ensuring relevance to digital health solutions. While Singapore's national IP protocol program actively regulates licensing and technology transfer, Philippines has a standard pathway for registration and regulations on licensing and technology transfer.

The general digital health technology regulations need to factor in the various aspects such as compliance, liability, regulatory oversight and national digital shared health platforms. An example would be the regulation in the US that mandates the use of Certified Electronic Health

Record Technology in accordance with the Health Information Technology for Economic and Clinical Health Act (HITECH) act on national and state level health information exchanges. Singapore has also been progressively deploying the national electronic health records platform which now covers 100% of public and over 90% of private sector hospitals and nursing homes. The Malaysian Society for Quality in Health is also setting up new standards for providers adopting digital health solutions such as HER, health information systems, etc. in 2023.

Digital tools specific regulations would be applicable to fields such as telemedicine, digital therapeutics, software as medical devices (SaMDs), mobile Health (mHealth) and AI. The US has certain laws with respect to telemedicine and mHealth – a series of state and federal level (HIPAA) laws detail requirements for licensure, platform usage, reimbursement provisions and cybersecurity with respect to telemedicine; for mHealth, a new enforcement policy was launched in 2021 for remote monitoring systems enabling expediated approvals and defining documentation requirements for usage in home settings. In South-East Asia, Malaysia and Singapore are the only two countries that regulate the telemedicine practice with laws on provider licence, incident mitigation measures and patient data protection laws. In 2021, Australia updated the Therapeutic Goods Act of 1989 to include specific regulations on data collection components used by SaMDs and risk classification rules.

The component on data protection and privacy would include data security, ethics, usage rights and cross-border data sharing practices. Both the US and Germany have established cybersecurity strategies albeit using differing approaches – while the US adopts a product lifecycle-based approach enabling rapid amendments to tackle evolving threats, Germany has established a strong culture of self-assessment with open communication channels to respond to breaches. Germany's 'Guidelines on the protection of health data' also provides details on patient rights to own the data, and on guidelines for data protection, transfer and utilization. In the APAC region, Singapore, Malaysia, Australia and the Philippines have data privacy acts in place with clear guidelines on health data and protocols for collection and usage including for online and digital health platforms. China's Data security law and personal data protection law lay out data storage, transfer and corporate data security control requirements.

The last key component on intellectual property needs to work towards protecting innovations, patents, and trade secrets. Most countries have trade secrets or confidentiality laws that are applicable to health data as well. However, in most jurisdictions, algorithms and Machine Learning (ML) models are not patentable. Even though Germany's patent act enforces subject matter patentability pertaining to software which can include SaMDs patents, it adopted a new

trade secret protection act in 2019 to clearly define digital specific trade secrets relevant to new business models relying on meta data and algorithms.

Moving forward, regulatory mandates for development of the ecosystem, talent building, creating a culture of accountability and assurance is required. Traditionally, regulations have been viewed as prohibitive. However, increasingly a range of tools such as sandboxing and consumer education are being used to facilitate the transition of prohibitive regulations to enabling regulations – governments are aware that the new regulatory frameworks must provide flexibility to enable innovation while ensuring patient safety and welfare and that this can be accomplished with the involvement and collaboration of multiple stakeholders, i.e., from industries, academia, public and private healthcare sectors. Regulations also need to consider ethical factors such as bias mitigation and fairness to enable responsible use of digital technology in healthcare.

6. Conclusion

Digitalisation of the healthcare sector is an exciting and impending development that offers promising solutions to address the challenges of an aging population, increasing costs, shortage of medical professionals and increased consumer expectations. Singapore's journey of digitalisation is realised through the Healthier SG program which in turn relies on the robust public healthcare system. However, challenges with yet unknown risks of the digitalisation include issues such as data breaches, cyber-attacks, explainability of AI, feasibility of precision medicine for population health, misuse of health data and more.

Regulations are evolving based on risks to patient safety in the digitally transforming healthcare sector. The complexity of digital health lies in its intersectional nature as it is difficult to classify it as a product or a service. Moreover, digitalisation is difficult to contain or compartmentalise. The most common conundrum refers to accountability of an AI assisted diagnosis on who is responsible for such a diagnosis, is it the developer, the implementing institution or the doctor. While policy makers are grappling with several issues, the innovations are occurring and are being implemented to ultimately improve population health. There are no simple answers to the question of whether we are ready for a digital health future, nor are there clear directions for transforming healthcare for the next decade. While what is on the horizon is recognisable, the boundaries keep shifting when it comes to technological advances and global circumstances. The COVID-19 pandemic leapfrogged digitalisation of several healthcare services and also motivated patients and consumers to adapt to the changing

scenario. The pandemic also reinforced the strength of global collaboration on healthcare initiatives. While regulations may not be in place yet, it is probably the essence of the future of healthcare, where risk-based regulations that can adapt to future advancements will co-exist with harder regulations that ensure the basic safety of the patient.

Authors

Dr Kavitha Palaniappan

Dr Chandrani Ghosh

Dr Praveen Kumar Gideon

A/Prof Silke Vogel

Centre for Regulatory Excellence

With contributions from

Prof John CW Lim

Centre for Regulatory Excellence

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References

Abernethy, A., Adams, L., Barrett, M., Bechtel, C., Brennan, P., Butte, A., Faulkner, J., Fontaine, E., Friedhoff, S., Halamka, J., Howell, M., Johnson, K., Long, P., McGraw, D., Miller, R., Lee, P., Perlin, J., Rucker, D., Sandy, L. and Savage, L. (2022). The Promise of Digital Health: Then, Now, and the Future. *NAM Perspectives*, 6(22). doi:https://doi.org/10.31478/202206e.

Blackbox Research (2022). *The future of telemedicine in Singapore - Blackbox Research*. [online] Blackbox Corp. Available at: https://blackbox.com.sg/everyone/the-future-of-telemedicine-in-singapore [Accessed 15 Aug. 2023].

Erdmann, A., Rehmann-Sutter, C. and Bozzaro, C. (2021). Patients' and professionals' views related to ethical issues in precision medicine: a mixed research synthesis. *BMC Medical Ethics*, 22(1). doi:https://doi.org/10.1186/s12910-021-00682-8.

Gopal, G., Suter-Crazzolara, C., Toldo, L. and Eberhardt, W. (2019). Digital transformation in healthcare – architectures of present and future information technologies. *Clinical Chemistry and Laboratory Medicine (CCLM)*, 57(3), pp.328–335. doi:https://doi.org/10.1515/cclm-2018-0658.

Gradillas, M. and Thomas (2023). Distinguishing digitization and digitalization: A systematic review and conceptual framework. *Journal of Product Innovation Management*. doi:https://doi.org/10.1111/jpim.12690.

Gunasekeran, D.V., Tseng, R.M.W.W., Tham, Y.-C. and Wong, T.Y. (2021). Applications of digital health for public health responses to COVID-19: a systematic scoping review of artificial intelligence, telehealth and related technologies. *npj Digital Medicine*, [online] 4(1). doi:https://doi.org/10.1038/s41746-021-00412-9.

MOH (n.d.). *MOH | Licensing Experimentation and Adaptation Programme (LEAP) - A MOH Regulatory Sandbox*. [online] www.moh.gov.sg. Available at: https://www.moh.gov.sg/home/our-healthcare-system/licensing-experimentation-and-adaptation-programme-(leap)---a-moh-regulatory-sandbox.

MOH (2022a). *MOH | News Highlights*. [online] www.moh.gov.sg. Available at: https://www.moh.gov.sg/news-highlights/details/keynote-speech-by-mr-ong-ye-kung-minister-for-health-at-the-2nd-asean-digital-public-health-conference-on-22-november-2022-2.40pm [Accessed 15 Aug. 2023].

MOH (2023a). *ABOUT HCSA*. [online] www.moh.gov.sg. Available at: https://www.moh.gov.sg/hcsa/about-hcsa.

MOH (n.d.). *MOH | Artificial Intelligence in Healthcare*. [online] www.moh.gov.sg. Available at:

https://www.moh.gov.sg/licensing-and-regulation/artificial-intelligence-in-healthcare.

MOH (2022b). *MOH | Artificial Intelligence in Healthcare*. [online] www.moh.gov.sg. Available at: https://www.moh.gov.sg/licensing-and-regulation/artificial-intelligence-in-healthcare.

MOH (2022c). *MOH | News Highlights*. [online] www.moh.gov.sg. Available at: https://www.moh.gov.sg/news-highlights/details/speech-by-mr-ong-ye-kung-minister-for-health-at-the-official-launch-of-the-sg100k-study [Accessed 30 Aug. 2023].

MOH (2022d). *The White Paper on Healthier SG*. [online] www.healthiersg.gov.sg. Available at: https://www.healthiersg.gov.sg/resources/white-paper/.

MOH (2023b). *MOH | Cybersecurity Resources*. [online] Moh.gov.sg. Available at: https://www.moh.gov.sg/licensing-and-regulation/cybersecurity-for-healthcare-providers/cybersecurity-resources [Accessed 22 Sep. 2023].

MOH (2023c). *MOH | News Highlights*. [online] www.moh.gov.sg. Available at: https://www.moh.gov.sg/news-highlights/details/speech-by-mr-ong-ye-kung-minister-for-health-at-the-integrated-health-information-systems-15th-anniversary-and-launch-of-new-identity-27-july-2023-9-40am-at-singapore-expo-hall-3 [Accessed 30 Aug. 2023].

MOH (2023d). *MOH | News Highlights*. [online] www.moh.gov.sg. Available at: https://www.moh.gov.sg/news-highlights/details/speech-by-dr-janil-puthucheary-senior-minister-of-state-ministry-of-health-at-ihis-microsoft-generative-ai-micro-conference-on-friday-7-july-2023 [Accessed 30 Aug. 2023].

MOH (2023e). *MOH | News Highlights*. [online] www.moh.gov.sg. Available at: https://www.moh.gov.sg/news-highlights/details/speech-by-mr-ong-ye-kung-minister-for-health-at-the-precision-public-health-asia-2023-conference-13-july-2023-8.55am-at-the-ng-teng-fong-centre-for-healthcare-innovation [Accessed 30 Aug. 2023].

MOH (2023f). *MOH | News Highlights*. [online] www.moh.gov.sg. Available at: https://www.moh.gov.sg/news-highlights/details/expenditure-on-and-utilisation-of-national-electronic-health-record-system [Accessed 30 Aug. 2023].

MOH (2023g). *MOH | News Highlights*. [online] www.moh.gov.sg. Available at: https://www.moh.gov.sg/news-highlights/details/reviewing-system-enablers-to-support-

healthcare-transformations---health-information-
bill#:~:text=The%20Ministry%20of%20Health%20(MOH [Accessed 22 Sep. 2023].

MOH, HSA and IHiS (2021). *Artificial Intelligence in Healthcare Guidelines (AIHGle)*.
Prof, A. and Ong, B. (2015). *National Telemedicine Guidelines*.

Stoumpos, A.I., Kitsios, F. and Talias, M.A. (2023). Digital Transformation in Healthcare:
Technology Acceptance and Its Applications. *International Journal of Environmental Research
and Public Health*, [online] 20(4), p.3407. doi:https://doi.org/10.3390/ijerph20043407.

Ta, A.W.A., Goh, H.L., Ang, C., Koh, L.Y., Poon, K. and Miller, S.M. (2022). Two Singapore
public healthcare AI applications for national screening programs and other examples. *Health
Care Science*, 1, pp.41–57. doi:https://doi.org/10.1002/hcs2.10.

Vrana, J. and Singh, R. (2021). Digitization, Digitalization, and Digital Transformation.
Handbook of Nondestructive Evaluation 4.0, pp.1–17. doi:https://doi.org/10.1007/978-3-030-
48200-8_39-1. www.dlapiperintelligence.com. (n.d.). *How is telehealth regulated? in
Singapore - DLA Piper Telehealth Around the World*. [online] Available at:
https://www.dlapiperintelligence.com/telehealth/countries/index.html?t=02-regulation-of-
telehealth&c=SG [Accessed 30 Aug. 2023].

Yong See, Q. (2020). Attitudes and Perceptions of General Practitioners towards the National
Electronic Health Record (NEHR) in Singapore. *European Medical Journal*, pp.86–93.
doi:https://doi.org/10.33590/emj/19-00184.

Zhang, J. and Zhang, Z. (2023). Ethics and governance of trustworthy medical artificial
intelligence. *BMC Medical Informatics and Decision Making*, 23(1).
doi:https://doi.org/10.1186/s12911-023-02103-9

Contact us

Tel: +65 6601 5147
Email: CoRE@duke-nus.edu.sg

Duke-NUS Medical School
8 College Road
Singapore 169857
www.duke-nus.edu.sg/core

centre-of-regulatory-excellence

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