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Khazanah Research Institute

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Putting Patients First: Principles for Future-Facing Electronic Health Records in Malaysia

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Summary

- Malaysia's government aspires for the nation to be digitally-driven and this encompasses a goal of improving healthcare delivery through digitalisation. A digital health records system is the bedrock for future healthcare and well-being management.

- Despite active planning of digitalisation initiatives for the Malaysian public healthcare sector, implementation has stagnated. Issues cited include slow uptake, lack of follow-through and reluctant budgetary commitment. As of 2020, only 25% of 146 public hospitals and 9% of 1,090 public clinics had been digitalised.

- A patient-centric system that gives patients control over their health data can empower them to manage their health better. Patient empowerment is especially important given increasing digital adoption and an aging society. Encouraging health literacy and self-care will also further MOH's efforts to have a lifetime health record to ensure better healthcare delivery and patient outcomes.

- A comparative analysis between Malaysia and four case study countries (Australia, China, Singapore and the United States of America) with varying healthcare delivery and digital health records systems highlights three specific areas for policy consideration.

- First, patient inclusion and empowerment. Any digital health system has to be inclusive by design, regardless of patient location, demographics and digital literacy. An inclusive system would also empower patients to increase their health literacy and better manage their own health.

- Second, data governance. The nation needs data protection laws that make provision for digitally collected and stored private health data. Crisis management plans and complaints processes should also be developed and implemented. Patients and healthcare practitioners alike should be educated on their rights and responsibilities with respect to health data.

- Third, system integration across the healthcare landscape and over the life course. Digital health records should follow patients throughout their life regardless of the sort of healthcare provision they seek and where they seek it. Responsible data sharing across facilities would enable the collection of comprehensive health data, in turn improving healthcare delivery and health outcomes.

Abbreviations

ABBREVIATIONS		
ADHA	:	Australian Digital Health Agency
API	:	Application Programming Interface
EHR	:	Electronic Health Record
EMR	:	Electronic Medical Record
FHIR	:	Fast Healthcare Interoperability Resources
HIE	:	Health Information Exchange
HIPAA	:	Health Insurance Portability and Accountability Act
HIS	:	Hospital Information System
HISPC	:	Health Information Standardisation Professional Committee
HWP	:	Health White Paper
ICD	:	International Classification of Diseases
ID	:	Identification
IHiS	:	Integrated Health Information System
IP	:	Internet Protocol
KK	:	*Klinik Kesihatan*
KP	:	*Klinik Pergigian*
LHP	:	Lifetime Health Plan
LHR	:	Lifetime Health Record
MHR	:	My Health Record
MOH	:	Ministry of Health
MP	:	Malaysia Plan
MyHDW	:	Malaysia Health Data Warehouse
MyHix	:	Health Information Exchange Platform
NEHR	:	National Electronic Health Records
NEHTA	:	National Electronic Health Transition Authority
NEI	:	National EMR Initiative
NHG	:	National Healthcare Group
ONC	:	Office of the National Coordinator for Health IT
PCEHR	:	Personally Controlled Electronic Health Records
PCIDA	:	Prevention and Control of Infectious Diseases Act 1988
PDPA	:	Personal Data Protection Act 2010
PHR	:	Personal Health Record
PPV	:	Pusat Pemberian Vaksin or Covid-19 Vaccination Centre
PSP	:	Pelan Strategik Pendigitalan or Strategic Plan for Digitalisation 2021-2025
RP4	:	Malaysia's Fourth Rolling Plan
SOP	:	Standard Operating Procedure

ABBREVIATIONS

TPC	:	Teleprimary Care
TPC-OHCIS	:	Teleprimary Care-Oral Health Clinical Information System
USA	:	United States of America

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1. Introduction

Over the course of a lifetime, a person generates billions of data points of behavioural information[1]. The advent of digital technology into everyday life has made it possible for all that data to be collected and analysed, mostly for commercial purposes. Recommendation algorithms used by social media and other platforms utilise these data points to curate and suggest content, predict preferences and nudge behaviours.

This sort of analysis would be useful in health settings, not just for the benefit of individuals but also for public health. Health apps already track exercise and sleep patterns and offer options to input other health and medical data as well. If these health data were to be integrated with medical information without compromising privacy, much more health research could be conducted in the interest of public health and patient welfare. Healthcare practitioners could have more information with which to make diagnoses and treatment plans whereas patients could have better control over their health. Also, public health and epidemiological research could be more precise, potentially leading to more effective policies.

Building a digital health ecosystem is a complex endeavour. Importantly, this begins with digitalising medical records. There are many justifiable concerns around data privacy and ethical use of data. In a society facing the threat of constant digital surveillance, it becomes ever more pressing that the design and governance of digital systems be done in the public interest.

Malaysia began its ambitious plans to incorporate technology, including digital health records, into public healthcare provision in 1997. Digital health records are foundational in achieving the Ministry of Health's (MOH) stated goal of optimising healthcare provision by upgrading hospital systems. However, in 2023, Malaysia still lacks a national digital health records system. With digital technologies transforming society, health systems cannot be left behind especially as Malaysia heads towards being an aging society.

Digital tools and technologies offer means of improving health literacy and giving patients more insight into and control over their health and well-being. This is especially useful given the variety of healthcare needs and options available in both the public sector and the private market.

However, for such a health system to achieve its potential, personal and private health data need to be collected, analysed and shared over patient's lifetime and across their healthcare providers. As with all matters involving personal data, good governance and cybersecurity safeguards are required.

This paper outlines three key considerations for the design and implementation of digital health records, specifically electronic health records (EHRs), in Malaysia's public healthcare system.

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[1] Zuboff (2019)

These are **patient inclusion and empowerment**, **data governance**, and **system integration** across the healthcare landscape and over the life course.

We undertake a review of countries that have implemented digital health records to assess how different forms of healthcare provision, as well as data privacy laws and regulations, impact the use of such systems by healthcare providers. In selecting Australia, China, Singapore and the United States of America (USA) as our case studies, we are able to compare how population size, healthcare provision models and the role of the federal government affect the rollout of digital health records.

2. Background

2.1. Dissecting the Differences Between Electronic Medical Records (EMRs), EHRs and Personal Health Records

Malaysia's government aspires for the nation to be digitally-driven and this encompasses a goal of improving healthcare delivery through digitalisation[2]. To achieve this, government publications such as the Health White Paper (HWP) released in 2023 have placed importance on setting up a system that digitalises patient records and integrates across healthcare facilities[3].

A digital health records system is the bedrock for future healthcare and well-being management. Digitalisation of health records has been gaining momentum worldwide through various approaches and this has resulted in the different types of health records. The terms electronic medical records, electronic health records and personal health records are commonly used, sometimes even interchangeably despite there being significant differences between them. In brief:

- **Electronic Medical Records (EMR)** are a digital version of a clinician's chart, meant to be used within a single practice and are limited to use within a single facility. An EMR can longitudinally follow a patient's healthcare journey as long as he or she continues receiving care at the same healthcare provider[4].
- **Electronic Health Records (EHR)** are a digital record of patient health that can follow an individual throughout their entire journey across the healthcare landscape through the enablement of seamless information sharing between healthcare providers and facilities. An EHR system is more comprehensive than an EMR as it is cross-institutional and provides a complete overview of a patient's medical history regardless of location of treatment[5].
- **Personal Health Records (PHR)** are a collection of a patient's medical history that is maintained and managed by the patient themselves or an authorised caregiver. As a more patient-centric extension of EHRs, PHRs can include data that are sourced from a healthcare provider's EHR, e.g. laboratory results and diagnosis, in addition to self-generated data, e.g. symptoms and at-home monitoring results[6].

A summary of the differences are shown in Table 1. While both EMRs and EHRs are owned and maintained by healthcare providers, PHRs tend to have patient-specific functionalities and are fully controlled by the patient. Between EMRs and EHRs, EHRs appear to be a more comprehensive solution for the modernisation of healthcare since they track patient needs over time and across facilities, ensuring thorough health services at all levels of care intensity[7].

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[2] Economic Planning Unit (EPU) (2021a)

[3] MOH (2023)

[4] Heart, Ben-Assuli, and Shabtai (2017); Garrett and Seidman (2011)

[5] Heart, Ben-Assuli, and Shabtai (2017); Garrett and Seidman (2011)

[6] Bouayad, Ialynytchev, and Padmanabhan (2017); Heart, Ben-Assuli, and Shabtai (2017)

[7] Ilyana Mukhriz (2021)

PHRs reside with the patient, and this means that patients are able to present their full medical data to multiple healthcare providers regardless of whether these providers have an EHR system in place or if their system is able to communicate with the patient's previous provider. Although PHRs promote continuity of care for the patient and empower patients to track their health at home through their personal devices, the setup of EHR systems remains crucial. Outsourcing the responsibility of data collection to patients could potentially pose problems in terms of inclusivity and data accuracy.

Table 1: Summary of terms involved in the digitalisation of health records

Term	EMR	EHR	PHR
Contributors	Healthcare provider	Healthcare provider	Healthcare provider and patient
Shared across facilities	✗	✓	✓
Access by patient	✗	Varies	✓
Follows patient over lifetime	✗	✓	✓

Sources: Ben-Assuli and Shabtai (2017); Bouayad, Jalunytchey and Padmanabhan (2017)

Malaysia has historically referred to its efforts of digitalising patient records using the term EMR. However, EMR may be a misnomer since the system's description of "ensuring seamless flow of information among healthcare facilities" points towards it being more of an EHR venture[8]. This paper will refer to Malaysia's effort as being an EHR venture henceforth.

In 1997, the government published Malaysia's Telemedicine Blueprint introducing the concept of a Lifetime Health Record (LHR), which were longitudinal medical records that would record detailed patient information each time a patient receives care. These LHRs would be used to feed into a larger Lifetime Health Plan (LHP) that would provide health plans personalised from womb to tomb, supporting individuals to take charge of their health in both wellness and illness[9]. The LHP envisioned by the government in the Telemedicine Blueprint was also proposed to ensure "access to an integrated set of medical records independent of time and location", indicating an EHR-like system[10].

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[8] Ilyana Mukhriz (2021)

[9] MOH (1997)

[10] MOH (1997)

Malaysia also uses the term health information exchange (HIE) which usually refers to a platform that is designed to electronically transmit patient information between hospitals and clinics[11]. Thus, HIE would fall under the umbrella of an EHR system since it allows cross-institutional data exchange.

2.2. The Potential Benefits of EHRs

Having an EHR system of good quality has been cited as crucial in determining the success of further digital health technology adoption, particularly since it serves as an infrastructural foundation for remote healthcare delivery and ensuring continuity of care[12]. For example, during the Covid-19 pandemic, having an existing EHR system allowed medical facilities to rapidly enable telemedicine delivery. Access to a patient's history, referral records and diagnostic data enabled operations to be scheduled without requiring a physical visit to the provider[13].

Not only would EHRs aid in shifting the care burden away from the healthcare sector, they would also act as a comprehensive patient registry to allow effective targeting of populations for healthcare screening. Decreasing the congestion of healthcare facilities, supporting self-management of disease at home and tackling disease at early stages are some of the uses of digitalised health records that would ensure that Malaysia's healthcare system is resilient to any future shocks such as a pandemic[14]. Although a high upfront investment is needed, digital health records have the potential for long-term cost savings such as reducing the need for storage space of paper records and physical record supplies[15].

2.3. Considering Risks and Pitfalls

A centralised healthcare database, although ideal in promoting cost-effectiveness and continuity of care, does not come without certain risks. The introduction of a digital layer onto an already complex healthcare system potentially opens up sensitive patient data to threats from cybercriminals. MOH has already acknowledged this risk[16]. Additionally, a digitalised system also poses usability issues which could affect healthcare provider workflows and quality of care.

There are also concerns of whether the implementation of digitalised patient records would universally benefit all levels of society in Malaysia. The digital divide resulting from inequalities in access and literacy in the fields of healthcare and communication could also transform into a care divide, where quality of care received becomes reliant on a patient's ability to utilise their

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[11] Salleh, Abdullah, and Zakaria (2021); Nurul Ismail and Nor Hazana Abdullah (2017)

[12] Zhang and Saltman (2022); Al-Shorbaji (2021)

[13] Smith et al. (2020)

[14] A separate piece on the benefits of EHR implementation can be found in a previous Views piece titled Digitalised Health Records: Does Malaysia Need It?.

[15] Choi, Lee, and Rhee (2013); Kazley et al. (2014); Lammers and McLaughlin (2017)

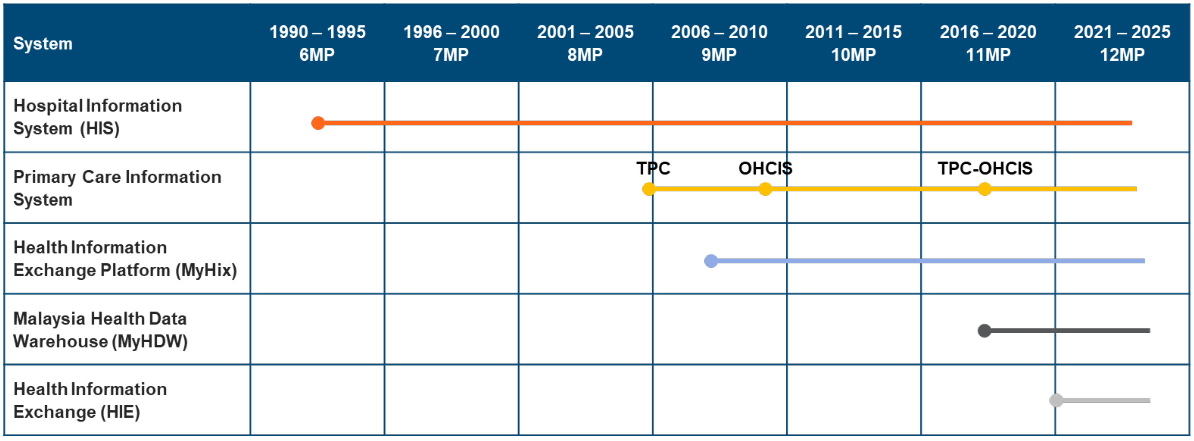
[16] Bernama (2017)

health records. These risks and pitfalls need to be proactively addressed in the design of a nationwide EHR system[17].

2.4. Malaysia's Efforts to Digitalise Health Records

Since the late 1990s, the Malaysian government has demonstrated its intent to digitalise the country's healthcare sector, although efforts have waxed and waned. Table 2 summarises the health record digitalisation initiatives that have been launched in Malaysia over the years.

Table 2: Timeline of government initiatives to digitalise patient health records in Malaysia



Sources: Ilyana Mukhriz (2021); Internal MOH documents (2022)
Note: See Section 3.2 for further discussion on HIE
Abbreviations: Malaysia Plan (MP); Teleprimary Care (TPC); Oral Health Clinical Information System (OHCIS)

The introduction of HIS in government hospitals was one of the earliest steps towards electronic collection, storing and retrieval of patient data. This was followed by the implementation of cloud-based digital records systems, Teleprimary Care (TPC) and Teleprimary Care-Oral Health Clinical Information System (TPC-OHCIS), in public primary care and dental facilities beginning in 2005.

EHR-friendly systems in public clinics or *klinik kesihatan* (KK) and dental clinics were built to provide access to patient records across facilities. But in hospitals, HIS only allowed the creation of EMRs. Thus, in 2008, Malaysia launched MyHix as a homegrown platform that would allow the integration of hospitals and clinics using HIS or TPC-OHCIS, enabling electronic transmission of patient information between public healthcare facilities[18].

It should be noted that MyHDW is not considered a digital health record, unlike the other initiatives listed in Table 2. However, MyHDW has been included since it is a platform that aims to be a centralised digital database for aggregated data on patient movement within healthcare facilities in the country[19].

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[17] A separate piece on the risks and pitfalls of EHR implementation can be found in a previous Views piece titled Challenges Arising From Digitalising Health Records.

[18] Ilyana Mukhriz (2021)

[19] Further analysis on Malaysia's efforts to digitalise health records in the past can be found in a previous discussion paper titled Electronic Health Records: Planning the Foundation for Digital Healthcare in Malaysia.

Despite active planning of digitalisation initiatives for the Malaysian public healthcare sector, implementation has stagnated. Issues related to uptake, follow-through and budgetary commitment have been cited. As of 2020, only 25% of 146 public hospitals and 9% of 1,090 public clinics had been digitalised[20]. An even smaller proportion of public facilities were integrated with the MyHix platform, thus preventing the benefits of information sharing to be reaped since it was unable to follow a typical patient's movement throughout the healthcare landscape[21].

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[20] The Star (2023); Parliament of Malaysia (2020)

[21] Ilyana Mukhriz (2021)

3. Latest Developments in Malaysia's EHR

Overall, much of the developments in hospital digitalisation have been through institution-based systems. HIS and TPC-OHCIS require public healthcare facilities, many of which are considered legacy facilities, to upgrade their infrastructure. These upgrades extend beyond installed equipment, and include structural suitability for digital systems, such as plug point availability and signal quality within the facility itself. High upfront costs have consistently been cited as a barrier, even three decades after these systems were first envisioned[22].

Given the challenges of high costs, legacy physical infrastructure, and uneven internet performance, Malaysia's recent efforts to implement EHR have departed from facility-based systems. To adapt to the local mobile-first digital landscape, systems that do not require a lot of storage space or high processing power were introduced. Turning to cloud storage and accessing patient data through a browser instead of requiring software installation on multiple machines is intended to ease EHR implementation in legacy facilities.

MOH has continued its efforts to install digital systems that would increase healthcare delivery efficiency, specifically by allowing patient records to be shared across facilities and providers. Specific reference to this initiative, termed EMR but better understood as EHR, has frequently been made in post-Covid government publications. This includes the 12th Malaysia Plan (12MP), MOH's Strategic Plan for Digitalisation 2021–2025 (PSP 2021–2025) and the HWP[23].

This section will focus on two of the latest developments in Malaysia's journey towards an EHR system in the public sector following the Covid-19 pandemic. The first is the MySejahtera application which was launched in April 2020 and the second is a Health Information Exchange (HIE) project under a broader healthcare digitalisation initiative that was also announced in 2020.

3.1. Malaysia is Mobile-First: The Rapid Scalability of MySejahtera

One example of the scalability of a mobile health application can be seen in the rapid roll-out and take-up of MySejahtera. MySejahtera was launched in April 2020 as a solution to the need for scientific data to tackle Covid-19 outbreaks. Originally designed as a monitoring tool, MySejahtera allowed the Malaysian government to conduct contact tracing and detect spikes in Covid-19 cases. This involved participatory surveillance, where citizens would scan QR codes upon entry to any premises, which was mandated beginning from August 2020 to April 2022[24].

The MySejahtera application operated under the enforcement of Act 342 and collected personal data from millions of Malaysians, including their name, phone number, identity card or passport number, current location and self-declaration of infection risks[25].

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[22] The Sun Daily (2023b)

[23] EPU (2021b); MOH (2022); (2023)

[24] Muhamad Khair, Lee, and Mokhtar (2021); Chin and Chan (2023); The Star (2020); internal MOH documents (2022)

[25] Muhamad Khair, Lee, and Mokhtar (2021)

Act 342, or the Prevention and Control of Infectious Diseases Act 1988 (PCIDA), granted the Minister of Health full power to enforce a set of rules for any region in Malaysia in the event of an infectious disease outbreak. For example, conducting spot-checks on vehicles or ordering restrictions in movement to avoid the spread of disease. Under the act, enforcers are given jurisdiction to request any information related to the prevention and control of disease and every person in the country is required to comply. Thus, MySejahtera was able to obtain real time data once made mandatory[26].

The role of MySejahtera as a contact tracing application was expanded further between June and October 2020. Subsequent updates to the application allowed users to register dependants who did not have a mobile number or access to a smartphone, such as elderly family members or children, in addition to enabling at-home monitoring of individuals under quarantine[27]. The latter was particularly useful in relieving the burden on the healthcare system by allowing those with less severe symptoms to be isolated in their own residences or selected facilities. Although other tracing initiatives were also launched at state level, only MySejahtera was mandated nationwide[28].

MySejahtera had the highest install penetration (85%) and open rates (92%)[29] among the top Covid-19 applications downloaded worldwide in 2021 according to a report by data.ai, a global data aggregation, reporting and analytics company. This illustrates the readiness of the Malaysian population to adopt a mobile application. Government requirements for mandatory check-ins during the early stages of the Covid-19 pandemic were instrumental in widespread adoption of this digital health record application.

Nonetheless, its efficacy is clear in the detection of positive cases during the peak of the pandemic as well as how Covid-19 vaccinations were rolled out. In November 2020, three months after check-in through MySejahtera was made mandatory, the Director General of Health announced that between 15.1% to 37.8% of positive cases had been detected through contact tracing via MySejahtera[30].

With regard to vaccination, following the launch of the vaccination registration module in February 2021, 1.067 million Malaysians had registered within two days[31] and the country achieved its target of 300,000 daily vaccinations in July 2021[32]. Although the process was not perfect[33], the ability to register and receive personal vaccination information via mobile

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[26] MOH (1988)

[27] Internal MOH documents (2022)

[28] Muhamad Khair, Lee, and Mokhtar (2021)

[29] Install penetration refers to the percentage of actively used smartphone or tablet devices within a chosen market that had installed a specific application during a selected time period. Open rate is the percentage of devices with said application installed that opened the application at least once during a selected time period (data.ai, 2017).

[30] Director General of Health (2020). Note: The variation in percentage of cases detected is due to the fluctuation in both total daily cases and total cases using MySejahtera.

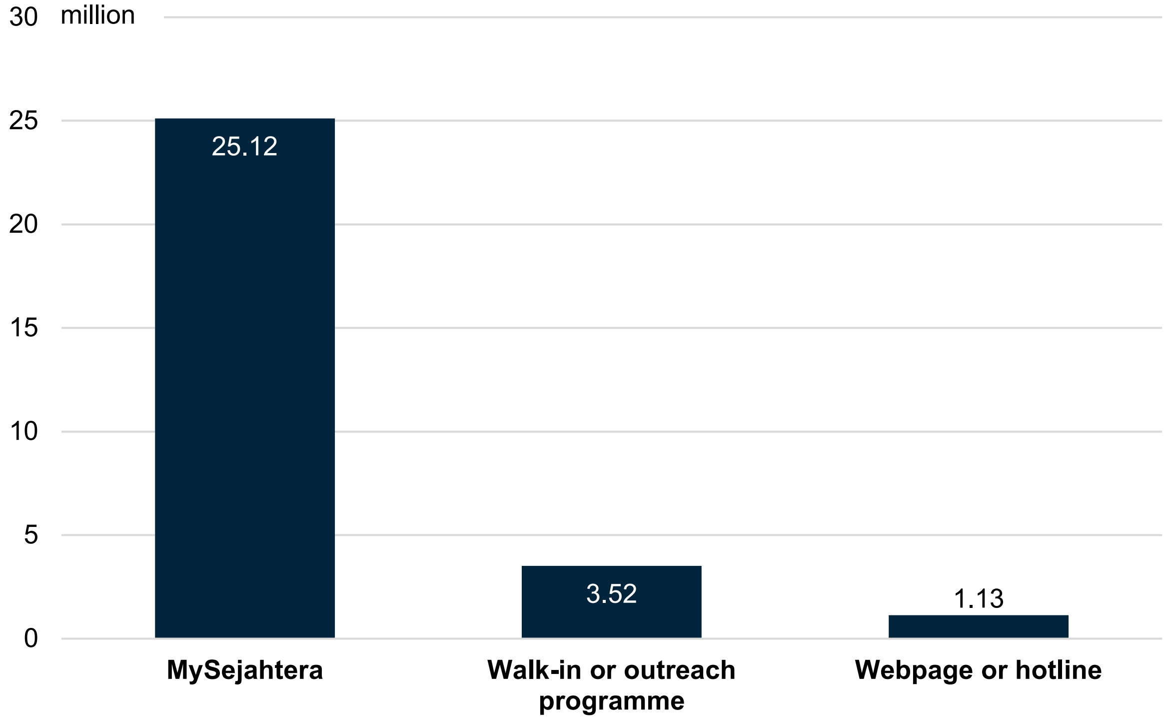
[31] Malay Mail (2021); Bernama (2021)

[32] New Straits Times (2021a)

[33] New Straits Times (2021b); (2022a); Malaysiakini (2021)

application undoubtedly eased the process of vaccination rollout. As seen in Figure 1, the vast majority of registrations (83.5%) were made via MySejahtera.

Figure 1: Mode of registration for Malaysia's Covid-19 vaccination programme, 2022



Source: Auditor General of Malaysia (2022)
Note: Based on data up until August 2022

As the country shifted towards embracing endemicity of Covid-19, the requirement to check-in at all premises with the MySejahtera application was lifted[34]. The government then stated its intention to turn MySejahtera into a public health application in a bid to embrace digital health post-pandemic[35]. This included an expansion of functions to include infectious disease surveillance, vaccination records under the National Immunisation Programme as well as health records[36]. These health records consist of information from healthcare providers such as health screening reports and laboratory results as well as information that could be added by users themselves such as height, weight and blood type.

Public trust and buy-in is needed for such a system to be sustainable. There have been some questions asked about how securely health data were being managed. The Auditor General's report released in 2021 flagged a few data security issues that were found in the MySejahtera system. A summary of the main issues found by the audit is shown in Figure 2.

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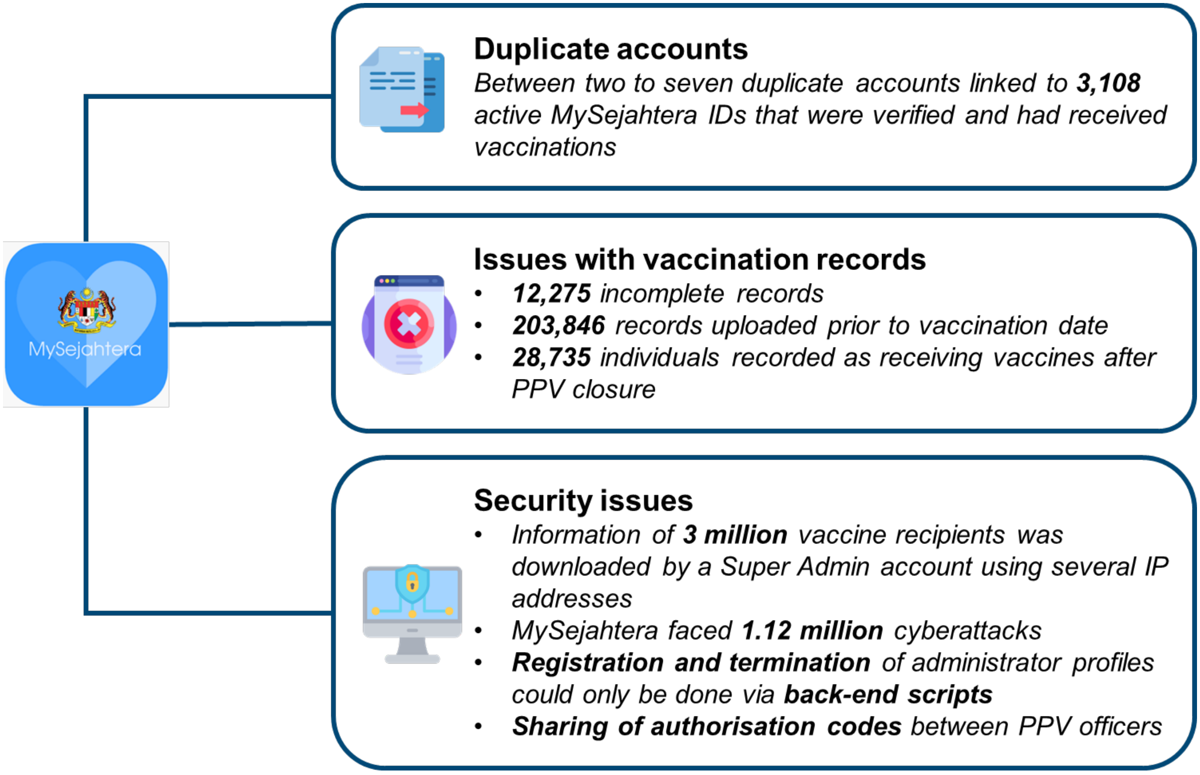
[34] The Star (2022a)

[35] The Malaysian Reserve (2022)

[36] The Sun Daily (2023a); The Star (2022b)

Figure 2: Summary of main issues faced by MySejahtera, 2022



Duplicate accounts

*Between two to seven duplicate accounts linked to **3,108** active MySejahtera IDs that were verified and had received vaccinations*

Issues with vaccination records

- ***12,275** incomplete records*
- ***203,846** records uploaded prior to vaccination date*
- ***28,735** individuals recorded as receiving vaccines after PPV closure*

Security issues

- *Information of **3 million** vaccine recipients was downloaded by a Super Admin account using several IP addresses*
- *MySejahtera faced **1.12 million** cyberattacks*
- ***Registration and termination** of administrator profiles could only be done via **back-end scripts***
- ***Sharing of authorisation codes** between PPV officers*

Source: Auditor General of Malaysia (2022)
Abbreviations: Identification (ID); Covid-19 Vaccination Centre or Pusat Pemberian Vaksin (PPV); Internet Protocol (IP)

Issues of note included the sharing of administrative accounts to third party and general users, shared user accounts for on-duty officers at vaccination centres as well as the downloading of information of 3 million vaccine recipients by a “Super Admin” account. MOH was advised to reassess the level of security for the MySejahtera app and to subsequently increase it[37].

Even if the public is not greatly concerned about data privacy and data security, any nation-wide health records system should institute data protection safeguards. This includes being transparent with the public on who has access to their health records, what the records are being used for, and a crisis management plan should the system be compromised.

3.2. A Lightweight and Interoperable Transition: HIE

Despite the introduction of a mobile health application during the Covid-19 pandemic, EHR implementation in Malaysia remains largely facility-based. One priority of government efforts to implement EHR has been to enable patient data sharing across facilities.

A National EMR Initiative (NEI), planned since before the pandemic in 2019, was part of MOH’s PSP 2021-2025. The PSP 2021-2025 highlighted the issue of unintegrated, manual and decentralised information systems within the healthcare landscape, proposing the NEI as a solution to enable data sharing[38].

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[37] Auditor General of Malaysia (2022)

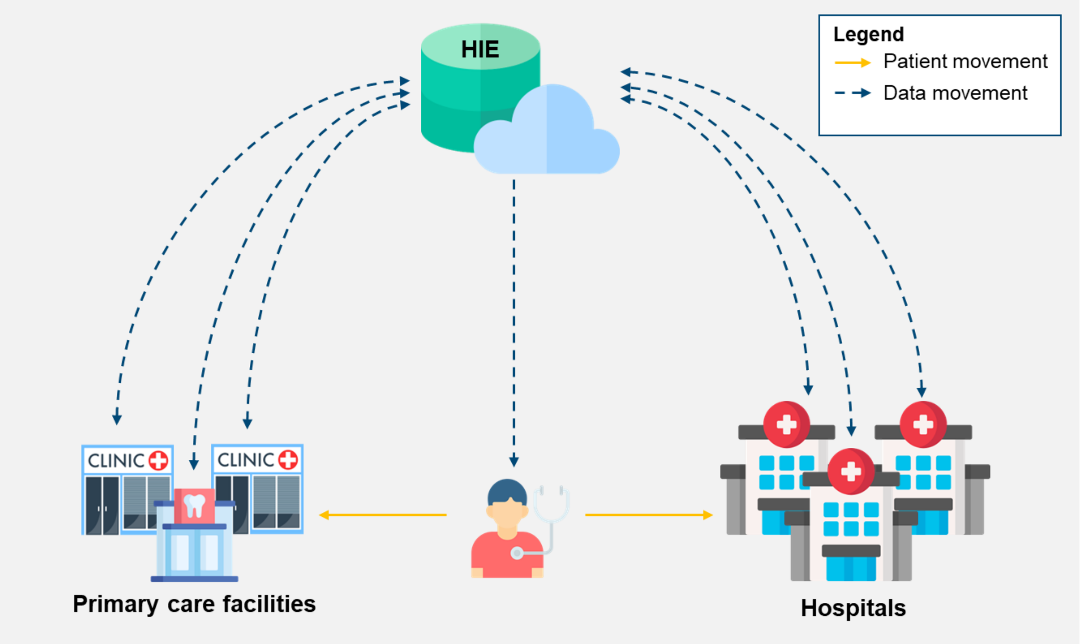
[38] Internal MOH documents (2022)

According to MOH, EMR was defined as an "electronic record of health-related information on an individual that conforms to nationally recognised interoperability standards and that can be created, managed, and consulted by authorised clinicians and staff across more than one health care organisation"[39]. As previously discussed, the idea of a cross-institutional record of patient health is in line with the idea of an EHR system although the government may not refer to it as such.

This NEI was designed as a two-phase process. Phase 1 would be the pilot stage with upgrades and expansion of HIS or TPC-OHCIS systems[40] in seven hospitals, 42 KKs, 11 *klinik pergigian* (KP) and 37 clinics in Negeri Sembilan. Phase 2 would kickstart the nationwide rollout of the project. The goal for this initiative was to have an EMR/EHR system in the Negeri Sembilan facilities by 2023 and in all hospitals nationwide by 2026[41]. An allocation of RM140 million was received by the NEI under Malaysia's Fourth Rolling Plan (RP4)[42].

A component of interest in the NEI is the development and integration of a HIE platform. A simplified overview of how the HIE would function is shown in Figure 3. HIE would succeed the aforementioned MyHix platform. Its ability to enable the sharing of patient health records between healthcare facilities places it under the EHR category.

Figure 3: An illustration of data flow across the healthcare landscape enabled by the HIE system



Source: Authors' illustration based on internal MOH documents (2022)
Note: All public primary care facilities (includes KKs and KPs) are planned to be equipped with TPC-OHCIS whereas all public hospitals are planned to be equipped with HIS. Both TPC-OHCIS and HIS are envisioned to eventually feed into the HIE platform.

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[39] Internal MOH documents (2022)

[40] TPC-OHCIS was branded as a cloud-based, centralised database allowing access to patient records at any point of care and would be categorised under EHRs. HIS is limited to patient records use within a facility and would be categorised under EMRs.

[41] Internal MOH documents (2022)

[42] Internal MOH documents (2022)

In summary, as a patient moves between primary care facilities and hospitals over their lifetime, the details of their encounter at each point of care would be added to a comprehensive health record. This health record would be uploaded from the facility's system, either HIS in the hospital setting or TPC-OHCIS in a primary care setting, on to the HIE platform. Subsequently, if the patient visits another facility, their new care provider would be able to access the information of their previous visit via the HIE platform, ensuring that healthcare providers are aware of their current and historical health status[43].

The HIE platform is planned to be used in conjunction with three service portals, summarised in Table 3. The RekodPesakit and RekodKesihatan portals are typical of previous attempts at healthcare facility digitalisation, in the sense that they are provider-facing. However, the RekodSaya portal shifts away from considering only care delivery towards patient empowerment.

Table 3: User portals in the HIE platform

Portal	User	Function	Key Components
RekodPesakit	Healthcare provider	For the creation, management and transmission of health records	• Patient registration • Medical record *Includes observations, vital signs, laboratory and diagnostic results, allergies, immunisation records, medication and blood donation/transfusion.* • Scheduling and Appointment • E-referral • Billing
RekodKesihatan	Management personnel	For providing critical reporting metrics information for performance and decision making	• Analytical reports • Executive dashboard *Includes summary of both clinical and non-clinical information such as blood stock, diagnosis and referral patterns*
RekodSaya	Patient	For enabling access to health records	• Blood donation information • Health risk assessment • Appointment and booking • Facility directory • Personal health record *Includes medical record*, lab results and medication lists*

Source: Internal MOH documents (2022)

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[43] Internal MOH documents (2022)

Using RekodSaya, a patient can access certain portions of their health records, such as their last visit to a healthcare facility, their diagnosis, laboratory results and any medications prescribed[44]. This enables, for example, children of elderly parents to help monitor their parents' health if needed. It should be noted that the medical records created by the healthcare provider may not be available to the patient in their entirety. The full medical record may contain detailed information that might be useful to doctors but that might not be necessary for the patient. Nonetheless, the patient-facing aspect of the HIE platform is a positive step towards realising a holistic EHR system.

3.3. Moving Forward

MOH has evolved its approach over the years to realise its long-standing vision of establishing a system that would allow data sharing across its many hospitals and clinics to enhance patient care throughout the nation.

The three main approaches (Table 4) towards realising this system have been: 1) to establish hospital-wide, standalone information systems within individual healthcare facilities and enable record sharing between facilities via a cloud platform, e.g. HIS; 2) to encourage the use of a patient-held mobile application that would contain their medical records i.e. MySejahtera; and 3) to create a web-based platform that would allow access to medical records by not only healthcare providers but also patients, i.e. HIE and its user portals.

In terms of categorisation, MySejahtera, HIE and HIS are all different. The medical records generated within a HIS would be categorised as an EMR since they can only be utilised within the facility they were generated in, unless enabled otherwise by an external platform. Since MySejahtera would be able to be managed and maintained by patients on their own mobile devices, it would essentially be considered a PHR. However, it would be an incomplete PHR lacking integration with healthcare provider systems.

Being web-based, the user portals introduced under the NEI would constitute an EHR system that has the best of both worlds. The portals can be accessed by patients, giving them more control in managing their health. Meanwhile, healthcare providers can easily input, transmit and view records of patients moving healthcare facilities, longitudinally following a patient as they receive care[45].

Moving towards a patient-centric system that gives patients control over their health data can empower them to manage their health better. Patient empowerment is especially important given increasing digital adoption and an aging society. Encouraging health literacy and self-care will also further MOH's efforts to have a lifetime health record to ensure better healthcare delivery and patient outcomes over the life course.

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[44] Internal MOH documents (2022)

[45] Stanley (2020)

Table 4: A comparison of MySejahtera, HIE and HIS

	HIS	MySejahtera	HIE
Brief Description	Electronic system within individual government healthcare facilities that are used in several departments within the facility itself	• Launched as Malaysia's main Covid-19 monitoring tool • Aimed to transition towards becoming a public health application	A platform under MOH that will be used to share health records across any facility being visited by a patient
Components	Dependent on extent of digitalisation of facility but generally includes patient management and clinical access information systems	• Contact tracing • Quarantine surveillance • Vaccination information and appointments • Medical records • Organ donation pledge • Blood donation information	The current HIE project scope involves: (1) a provider portal for patient registration, medical record creation and appointment scheduling (RekodPesakit) (2) a patient portal containing personal health records, appointment booking functions, facility directories and health information such as local campaigns and nationwide blood stock level (RekodSaya) (3) a management portal for overall metrics and reporting information for specific facilities (RekodKesihatan)
Category of Health Record Component	EMR	PHR	EHR
Access to Records	Healthcare providers	Healthcare providers and patients	Healthcare providers and patients

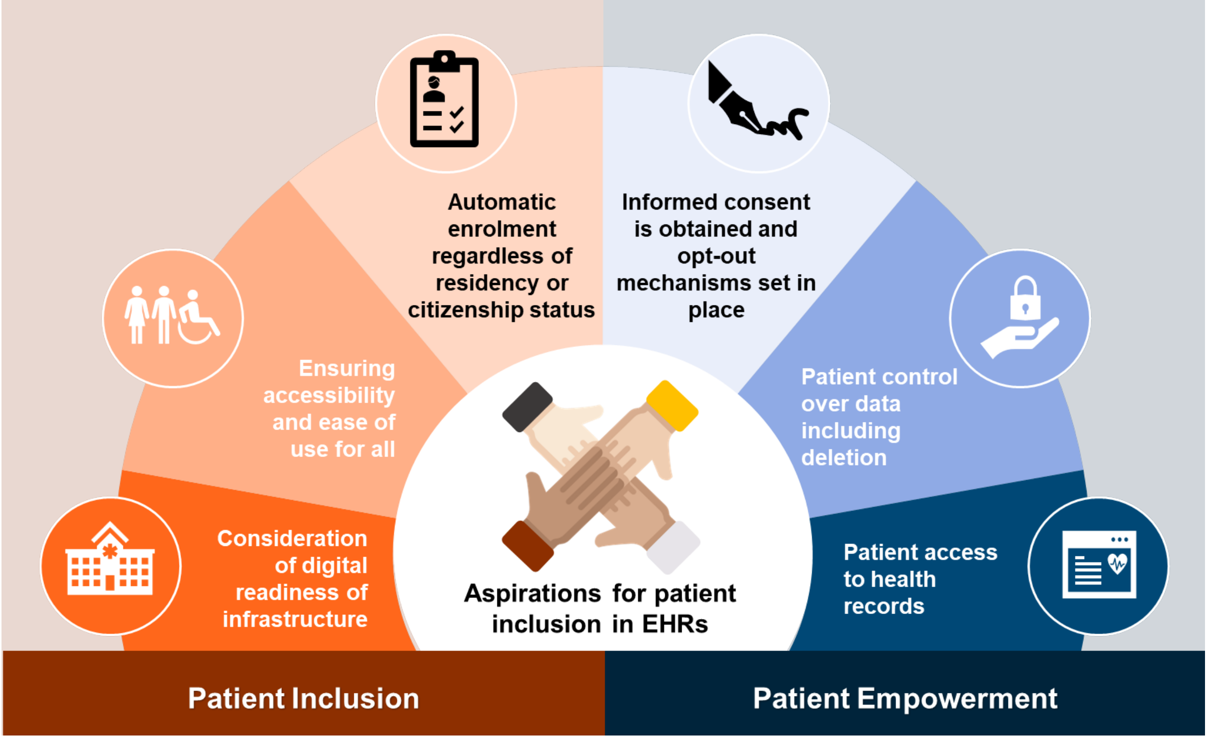
Sources: Singh, Couch and Yap (2020); Ismail, Abdullah and Shamsuddin (2015); Internal MOH documents; Ilyana Mukhriz (2021)

4. Critical Design Aspects

4.1. Patient Inclusion and Empowerment

It is important that EHR systems and policies promote inclusivity, focusing on benefiting the many instead of the few. In countries such as Australia, China, Singapore and the USA[46], efforts have been made to ensure equality in access or use of EHR systems. Selected focus areas are illustrated in Figure 4 and will be discussed further in this section.

Figure 4: The vision for patient empowerment and inclusion in Malaysia's EHR



Source: Authors' visualisation

Through the Basic Medical Healthcare and Promotion of Health Law the Chinese government has provided guidelines for promoting equitable access to healthcare information technology (e.g., EHR). This has contributed to the rapid development of health information infrastructure within the rural parts of China[47]. Another example of inclusion is Singapore's move to ensure that its EHR system is available to all within the country, regardless of residency or citizenship status. Generally, most patients will have access to EHRs if they consult with or attend an institution that participates in an EHR system[48].

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[46] These four countries will subsequently be collectively referred to as the "case study countries" in subsequent paragraphs whereas when individual countries are referenced, they will be mentioned by name. More details on specific countries are available in the appendix.

[47] Constitution of the People's Republic of China (2019)

[48] Integrated Health Information System (n.d.)

Aside from that, **many countries have set requirements for the implemented EHR systems to be standardised and patient-centric**. The US Congress, for example, introduced the 21st Century Integrated Digital Experience Act 2018 which requires all executive agencies to ensure accessibility and ease of use in designing systems and websites[49]. For Australia's EHR system, 17 different community languages are displayed in their communication materials in an attempt to promote inclusion between communities[50].

Even during the late 1990s, the Malaysian government had set a vision for its healthcare system to empower individuals and the community to take control of their health by providing access to timely information[51]. The more recent HWP released in 2023 echoes this move towards patient awareness and preventive care, in part through leveraging technology such as digital health records[52].

The effort to prioritise systems rollout within public healthcare facilities is considered the most inclusive approach since most of the Malaysian population have been shown to utilise these facilities compared to those offered by private providers[53]. However, this is still a significant undertaking due to Malaysia's varied geographical layout and outdated public infrastructure.

There are currently no specific acts or regulations promoting digital patient inclusion in Malaysia. Materials published in the case of MyHix included pamphlets and posters in Malay, English, Mandarin and Tamil. The same approach should be taken with the HIE initiative, with the addition of more materials targeted towards indigenous communities such as Orang Asli. Accessibility for those with disabilities should also be considered.

Besides promoting the inclusion of patients within the EHR system, **there also has to be a focus on empowering patients to use EHRs**. Patient empowerment, which allows people to gain greater control over decisions and actions that affect their health, has fast become a prominent paradigm within the global approach to public health[54]. Efforts have been made to alleviate the demand for professional health services and reduce the impact of chronic conditions on patient life. Thus, the focus has shifted towards creating a community of patients that is more informed, involved and interactive with healthcare providers[55].

In this regard, the introduction of digitalisation within the healthcare industry provides the perfect opportunity for enhancing patient empowerment, particularly when it comes to EHRs. Traditional paper-based systems have neglected to cater to patient-centricity as they did not necessarily allow patients to access their health records to encourage self-management of health or promote good patient-physician interactions[56].

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[49] US Congress (2018)

[50] Walsh et al. (2021)

[51] MOH (1997)

[52] MOH (2023)

[53] Nazihah and Ilyana Syafiqa (2021)

[54] WHO Europe (2006)

[55] Wakefield et al. (2018); Mola, De Bonis, and Giancane (2008)

[56] Manga and Sun (2020)

The self-management aspect introduced with EHRs holds the potential for those with chronic diseases, such as non-communicable diseases that have been on the rise in Malaysia, to effectively manage disease progression and improve clinical outcomes[57]. The WHO Europe has previously cited studies that associate patient self-empowerment, self-management skills and treatment satisfaction with improvements in disease control, knowledge and need for medication in diabetics[58].

To reap the full benefits of EHRs, **policies and systems should be designed to provide individuals with the right to know and decide how their health information is being used**. In the case study countries, although registration into the system is automatic when receiving care from a participating facility, an opt-out option is provided for the patient. Information about the EHR system is often required to be made available and accessible to the general public. In most cases, healthcare providers and system operators are required to provide the patient with necessary information such as data collection methods and purposes, disclosure and data breach notifications in addition to the reasons for use. Informed consent must also be obtained for any action relating to an individual's health data[59].

In Malaysia, HIS[60] and HIE both apply implied consent when enrolling patients. Patients are automatically assumed to consent to their data being added to the system[61]. They can choose to opt-out if they do not consent, although their existing data will not be deleted (see section 4.2 for further discussion).

In the case of the more recent HIE, participating healthcare providers are required to display a banner in the waiting area with details of how the patient's record would be shared between facilities. The banner also includes a note specifying how patients should inform the provider if they do not want their information to be shared. This indicates a positive step towards ensuring transparency of patient data use and autonomy over one's own data.

The EHR systems in the case study countries have all allowed patients to view and access personal health information through a third party, hospital or government-owned app. Australia has been particularly prominent in setting out legislations specific to patient access of EHRs. This began with the My Health Records Rules 2017, which automatically registers patients into Australia's EHR system but provides the opportunity to opt-out of the system if desired[62].

In the following year, the My Health Records Amendment (Strengthening Privacy) Act 2018 was introduced to allow Australians to permanently delete their record at any time, prevent any commercial use of EHR data and automatically remove authorised representative access of EHRs on behalf of teens once they exceed the age of 14[63]. Australia's EHR model provides individuals

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[57] Toni et al. (2021); WHO Europe (2006)

[58] WHO Europe (2006)

[59] Constitution of the People's Republic of China (2014); Constitution of the Republic of Singapore (2019); Office of the Australian Information Commissioner (2017); Senate Bill (2018)

[60] In the case of HIS, the enabling of information sharing would occur through the MyHix platform.

[61] MOH (2017) and authors' correspondence with MOH (2022)

[62] Commonwealth of Australia (2017)

[63] Commonwealth of Australia (n.d.)

with ready access to their own health information but to be part of the system remains a choice. To our knowledge, the autonomy to permanently delete individual health records is unique to Australia[64].

Malaysia's MySejahtera and HIE have both followed this trend of patient-centricity in providing a patient-facing platform for access to personal health information. In MySejahtera's case, this would be via the mobile application developed by a third party whereas HIE offers a government owned web-browser based portal. However, as was the case with HIS, patients are unable to delete their health record[65] . Amendments to the medical record can also only be done as an addendum by a medical practitioner as the record itself is not editable. To our knowledge, no similar legislations have been publicly introduced in Malaysia to enforce patient autonomy to the extent seen in Australia.

Another potential area of empowerment for EHR use would be through granting patients autonomy over their own health data privacy. Specifically in Australia, patients themselves can set "advanced access controls" to restrict access for healthcare provider organisations involved in their care[66]. Also, these patients' core medical records (e.g. current and past medical history and medication, allergies, diagnostic investigation) can only be shared between healthcare providers through the portal's secured eReferral system[67].

A cross-country comparison of patient inclusion and empowerment criteria is shown in Table 5.

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[64] Note: Unique among the case study countries discussed in this paper.

[65] MOH (2017)

[66] Gallagher (2018a); Wolf and Mendelson (2019)

[67] My Health Record (n.d.)

Table 5: Comparison of patient inclusion and empowerment criteria for country EHR systems

EHR Criteria	Malaysia	Australia	China	Singapore	USA
Citizenship restrictions applied for registration	✓	✗	✓	✗	Varies
Enrolment is automatic at point of care	✓	✓	✓	✓	✓
Patient must give explicit consent	✗	✓	✓	✓	Varies
Patient has access to health data	✓	✓	✓	✓	✓
Patients are able to opt-out of the system	✓	✓	✓	✓	Varies
Patient's data can be deleted upon opt-out	✗	✓	✓	✗	Varies

Sources: Internal MOH documents (2022), MOH (2017), Government of Australia (2023), MOH-PRC (2009), Standing Committee of Shenzhen Municipal People's Congress (2021), Integrated Health Information System (2019), Liang et al. (2019), ONC (2014), Xu et al. (2013)

4.2. Data Legislation, Privacy, Security and Governance

The implementation of EHRs in the case study countries have typically been accompanied by many digital health legislations that outline their structure, security and interoperability[68]. In the context of privacy and security, enhanced protection (e.g., categorising health information technology under Critical Information Infrastructure)[69] and penalties for the unlawful misuse and negligence involving personal health data have been enforced. These legislations provide individuals with the right to privacy through the autonomy to make decisions about their data (e.g., prevention of sale of personal data[70]) and to be aware of any relevant issue regarding how data is being managed (e.g. data breach notifications[71]).

For instance, Australia's My Health Records Act 2012[72] details a top-level privacy framework on how entities can collect, use and disclose information in addition to outlining reporting frameworks for data breaches. Meanwhile China, in response to a series of health data breaches,[73] introduced multiple data legislations that posit national security and technical frameworks,

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[68] See Appendix for more detail

[69] Commonwealth of Australia (n.d.); Constitution of the People's Republic of China (2016a); (2020); (2015); Constitution of the Republic of Singapore (n.d.); US Congress (2015)

[70] Senate Bill (2018)

[71] Commonwealth of Australia (2012)

[72] Commonwealth of Australia (2012)

[73] Gkritsi (2020); Langley (2020); Yueyang Internet Police (2019); China News (2021)

review procedures, and definition for health information as a personality right (i.e., infringement can lead to legal actions taken under the perspectives of Tort)[74].

The personal data collected by the MySejahtera application introduced in Malaysia was stated to be governed under the PCIDA 1988 and the Medical Act 1971[75]. These two acts, which have been cited repeatedly in answers on the topic of data privacy, do not specifically have a provision regarding the security of personal data[76].

The Medical Act 1971 governs medical practitioners registered with the Malaysian Medical Council[77]. The Medical Act may be effective at ensuring that registered medical practitioners protect confidential information against "improper disclosure" and keep confidential information in secure custody at all times[78]. However, we posit that while the Act protects against disclosure by medical practitioners, it may not be sufficient to govern breaches of the database.

On the other hand, the PCIDA only deals with personal data, which may not always include health data. Citizens are required to provide personal data such as their name and address in order to aid in the control of disease outbreaks. This Act may not be relevant under non-outbreak conditions[79]. Additionally, the Act focuses more on the collection of public data and not necessarily on the protection of said data.

MySejahtera has stated that "the management of the data in the [application] is compliant to [the] Personal Data Protection Act 2010 (PDPA)"[80]. However, the PDPA is only applicable to commercial transactions and does not apply to the federal or state governments[81]. In the case of valuable personal health data, the assurance of compliance is not enough as the government is not bound to any laws in case of MySejahtera data misuse[82].

Intrinsically, EHR systems should also be integrated with security technologies (e.g., multi-factor authentication, auto-detection on suspicious use, data retention limit) and time-stamped audit logs as security measures. In the USA, the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[83] requires all healthcare entities to provide comprehensive security management protection and frameworks for EHRs. Additionally, the Health Information Technology for Economic and Clinical Health Act 2015[84] requires that EHR vendors meet specific security requirements to be certified. There are also state-specific laws such as in California which

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[74] Constitution of the People's Republic of China (2020); (2021a); (2021b); Kuhns (2018); Constitution of the People's Republic of China (2015); (2016a)

[75] MySejahtera (2022)

[76] Tong and Tay (2022)

[77] Tong and Tay (2022)

[78] Malaysian Medical Council (MMC) (2019)

[79] Tong and Tay (2022)

[80] MySejahtera (2022)

[81] KRI (2021)

[82] Tong and Tay (2022)

[83] Federal Register (2006)

[84] US Congress (2015)

outlines the requirements for organisations that transact a large amount of health data to provide annual metrics reports[85].

Malaysia has thus far focused on data protection measures implemented by healthcare facilities. For example, the MyHix policy requires participating facilities to undergo preliminary compliance audits to assess compliance to the User Access Control Policy defined for users of information systems within healthcare facilities. The MyHix platform also produces an audit trail to monitor unethical access to the database. Even then, it should be noted that the monitoring of data quality and incident response mechanism is up to the discretion of the facility itself[86]. Furthermore, it is unclear what crisis management plans are in place should there be a data leak, for example, should a healthcare worker share patient information on social media.

There are no requirements for healthcare providers or MOH to inform patients of any leakage of their personal health data. In terms of opting out from the MyHix system, patients are only allowed to do so before the discharge summary is uploaded into the main database. However, the upload is done automatically meaning that patients may miss the opportunity to opt-out. Additionally, once uploaded into MyHix, patients are not able to delete or restrict access to their records[87]. It is unclear whether the future HIE platform will include changes to this policy.

A cross-country comparison of data legislations, privacy, security and governance is shown in Table 6.

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[85] Senate Bill (2018)

[86] MOH (2011)

[87] MOH (2017)

Table 6: Comparison of data legislation, privacy, security and governance criteria for country EHR systems

EHR Criteria	Malaysia	Australia	China	Singapore	USA
Specific laws governing health data exist	✗	✓	✓	✗	✓
Cybersecurity requirements for EHR systems exist	✗	✓	✓	✓	✓
Audit trail exists	✓	✓	Unknown	✓	✓
Data access policies for patient exist	✓	✓	✓	✗	✓
Data sharing policies for healthcare practitioners exist	✗	✓	✓	✓	✓
Crisis management plans for data breaches or leaks exist	Unknown	✓	✓	✗	✓

Sources: MOH (2017), Commonwealth of Australia (2012), Australian Digital Health Agency (2023), Constitution of the People's Republic of China (2015, 2016, 2020), MOH of the People's Republic of China (2012), Government of Singapore (2012), US Department of Health and Human Services (2023), US Congress (2009, 2015)

4.3. Integration and Adoption Across the Healthcare Landscape

The main challenges observed within EHR systems are adoption, standardisation and interoperability. Adoption often requires seamless integration across public and private institutions within the healthcare landscape, which is expensive. Despite top-level policy to develop the hardware and frameworks required for health information technologies[88], limited funding can hinder universal adoption[89].

Governments in the case study countries have attempted to introduce incentive programs to encourage private adoption such as the USA's Medicare EHR incentive program, Singapore's early adopter incentive, China's per registration incentives for community health service centres, and Australia Practice Incentives Program[90].

However, private adoption of EHRs globally is still fairly low. For instance, only 29% of Australian private hospitals adopted EHR in 2016[91]. In Singapore, only 27% of private health providers adopted EHR and only 3% of these private providers actually contributed data towards the

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[88] MOH of the People's Republic of China (2009)

[89] Gao et al. (2013)

[90] CMS (2014); Integrated Health Information System (2019); Gao et al. (2013); Xu et al. (2013)

[91] Fry et al. (2014); Kariotis and Harris (2019)

database in 2019[92]. Malaysia has not embarked on these incentive programmes for the rollout of its systems and has not engaged with private providers, instead focusing on public facilities under the allocated budget for MOH. As mentioned in Section 2.4, uptake of systems within the public sector has also been low.

Attempts to expand EHR systems on a national scale have varied in the case study countries. Australia and Singapore have taken a centralised approach with a government-owned system[93] whereas in China and the USA, implementation has largely been decentralised, albeit adhering to standards set by their governments[94]. For example, China's government requires that individual vendors adhere to specific standards and requirements[95]. Meanwhile, the USA allows providers to adopt different systems from vendors certified by the Office of the National Coordinator for Health IT (ONC)[96].

Malaysia's dual healthcare system has led to a mixed approach of centralisation and decentralisation. Private healthcare facilities have been allowed to implement their own information systems for patient health data[97] but public healthcare facilities have mostly been reliant on systems rolled out by the government (e.g. HIS, MyHix, HIE).

On one hand, centralisation involves implementing a single unified database across facilities, building interoperability into the system directly. On the other hand, decentralisation allows facilities more flexibility in their choice of system and could speed up adoption. In order to achieve true continuity of care, patient records should be accessible at any facility. Thus, standardisation is crucial to achieve interoperability.

Digital systems within healthcare facilities should be standardised, consistent and user-centric. Currently in Malaysia, standards are provided only as recommendations. For example, the MyHix Standard Operating Procedure (SOP) does not require the use of specified medical standards, such as the International Classification of Diseases (ICD), but instead only encourages it[98]. This could prove a barrier towards ensuring seamless sharing of health information between providers, i.e. interoperability, especially between public and private since the latter often operates on independent systems. The more recent rollout of HIE involves compliance with the international Fast Healthcare Interoperability Resources (FHIR) technical standard[99].

As of 2023, private clinics and hospitals or healthcare providers that do not come under the purview of MOH are not able to participate in information sharing due to the Private Healthcare

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[92] See (2020)
[93] See (2020); Xu et al. (2013)
[94] Gao et al. (2013); Liang et al. (2019); Atherton (2011)
[95] Constitution of the People's Republic of China (2016a); (2016b)
[96] US Congress (2015)
[97] Gleneagles Hospitals (2023); New Straits Times (2022b)
[98] MOH (2017)
[99] Authors' correspondence with MOH (2022)

Facilities and Services Regulations 2005[100]. This means that a patient receiving surgery in a public hospital would face difficulty obtaining seamless follow-up care at a private clinic, and vice versa.

For Singapore, the system owned by the government provides a portal for bidirectional information flows that would also involve private healthcare providers[101]. China set up a Health Information Standardisation Professional Committee (HISPC) specifically for the task of ensuring standardisation in health information technology. Therefore, despite there being no national system in place, interoperability is ensured through the requirement for EHR system vendors to undergo testing and evaluation by the HISPC[102].

One approach to addressing the interoperability issue is to **implement cloud storage of health data, and to access the data using applications such as web browsers or mobile applications**. For example, Covid-19 vaccination records can be accessed by patients regardless of whether they are using an Apple or Android phone, and by healthcare practitioners via a browser on their computers. Similarly, HIE and its accompanying user portals use a web-based interface that allows healthcare practitioners and patients access to health records regardless of device or location.

A cross-country comparison of integration and adoption across the healthcare landscape is shown in Table 7.

Table 7: Comparison of integration and adoption criteria for country EHR systems

EHR Criteria	Malaysia	Australia	China	Singapore	USA
Centralised nationwide system exist	✗	✓	✗	✓	✗
Cross-facility data sharing exists	✗	✓	✓	✓	Varies
Incentives for take-up exists	✗	✓	Unknown	✓	✓
Standards requirement exists	✓	✓	✓	✓	✓

Sources: Internal MOH documents (2022), Ilyana Mukhriz (2021), MOH (2017), My Health Record (2018), Xu et al. (2013), Australian Commission on Safety and Quality in Health Care (2017), Gao et al. (2013), Liang et al. (2019), MOH of the People's Republic of China (2012), US Congress (2009), CMS (2014), US Department of Health and Human Services (2020)

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[100] MOH (2017)

[101] Stephanie (2017a)

[102] Dong (2014); The State Council of The People's Republic of China (2019)

5. Idealised Policy Framework for Digital Health Records Systems

An examination of EHR in the case study countries (Australia, China, Singapore and the USA) and Malaysia leads us to the following policy considerations that should underpin any nation-wide digital health records system.

5.1. Empower patients to monitor and manage their own health

Malaysia's EHR system should be inherently inclusive and available to all that are receiving care from healthcare facilities in the country. Barriers such as low internet connectivity, language limitations and citizenship status should not result in certain groups being excluded from the benefits of health record digitalisation. EHR governance frameworks should actively work to address these issues from design to implementation.

Current developments in health record digitalisation in Malaysia have embraced patient access to health data. This should be continued moving forward. Empowering patients should involve providing not just patients with access and ability to opt-out, but also considering access for caregivers to enable management of care at home. Public awareness campaigns are also a crucial component in the rollout of EHR systems to communicate the value of accessing individual health data.

The rapid rise in non-communicable diseases seen in the Malaysian population requires improved long-term patient self-management and active at-home care. The introduction of EHRs is a step towards empowering and enabling individuals to be responsible for their health, shifting the burden of care away from limited secondary and tertiary care facilities.

5.2. Allow patients some control over their own data

Malaysia's HWP envisions a reform of the healthcare system towards more person-centred care, which requires shifting away from medical paternalism to patient autonomy[103]. Thus, EHRs should promote this reform by providing patients with access to their health records. Access to personal health information has been associated with positive health outcomes. It provides more informed patients increased opportunities to engage with healthcare practitioners on their health[104].

Patients should be granted control over their data, with the ability to set limits as to who can access their information. Audit trails can be provided to patients to give an overview of who has accessed their records over time. Data deletion options should also be offered to the patient, although this needs to come with appropriate education on the potential effects of record deletion on quality of care.

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[103] MOH (2023)

[104] D'Costa, Kuhn, and Fritz (2020); Kim and Lee (2023)

5.3. Build trust in the system by ensuring data are protected

Public trust has been cited as crucial for the successful adoption of health information technology, especially EHRs which involve personal and private data[105]. Thus, to address concerns around data privacy and protection, updated digital health specific legislations need to be introduced and communicated to the public. Current provisions may not be comprehensive enough to include how entities can collect, use and disclose health information.

As part of critical national information infrastructure, health services, including digital systems, require fit-for-purpose cybersecurity safeguards and processes in place. Disruptions to these systems could have serious consequences for national security and stability. Crisis management plans need to be detailed and shared with stakeholders to help build trust and to prevent negligence involving personal health data.

5.4. Allow health data to follow the patient across the healthcare landscape over their life course

Digital health records make it easier for comprehensive medical and health data to follow a patient throughout their life course. From infant vaccinations to childhood injuries to adult screenings and into old age, patients and their healthcare providers can track health histories to improve health outcomes. These health histories could eventually include not just professional medical diagnoses and treatments but self-reported health behaviours such as exercise and diet.

An integrated system that allows data sharing across facilities and healthcare providers also gives patients more options in their choice of health management. Anecdotal evidence suggests that patients are reluctant to seek specialist treatment, for example for mental health concerns or if they have long medical histories, simply because they do not want to rehash their entire medical history with a new healthcare professional. On the other side of the table, without comprehensive lifetime health records, healthcare practitioners may be concerned that they are not getting a full picture of a new patient's medical history. The proposed National Digital ID could potentially bridge this gap but requires further research and testing[106].

Thus, it is important to increase the number of healthcare facilities being digitalised, increase the number of patients being enrolled into digital health records systems and ensure that relevant health data can be shared as needed. As a start, it may be worth revising the Private Healthcare Facilities and Services Regulations 2005 to include provisions for responsible and appropriate data sharing between public and private facilities, with patient consent.

5.5. Other best practice considerations

Three further observations from the case study countries are worth highlighting for consideration in Malaysia: the means of funding and procurement within a public healthcare

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[105] Kerasidou and Kerasidou (2023); Belfrage, Helgesson, and Lynøe (2022)
[106] PWC (2020)

system, assumptions of supporting infrastructure and the need for redundancies or manual back-up systems.

First, on the means of funding and procurement within a public healthcare system. MOH should decide on the procurement process and system vendors to ensure interoperability. Facilities should be responsible for maintenance and upgrades of the system and its supporting infrastructure, with appropriate budget allocations from MOH. The facilities should also manage monitoring and evaluation of the system to ensure it is achieving the desired objective of improved healthcare delivery. For example, by conducting efficiency audits as determined by the auditor-general's office.

Second, on supporting infrastructure. For digital health systems to be successful, there must be stable and reliable infrastructure, such as a constant supply of electricity, high speed internet connectivity and up-to-date secure digital devices. Furthermore, it is assumed that patients and healthcare providers have sufficient digital and health literacy to reap the benefits of a digital health records system. These are currently policy objectives that Malaysia is still working towards.

Third, on the need for redundancies of manual back-up systems. No digital system is foolproof, and, as mentioned earlier, health services are a component of critical national information infrastructure. As such, redundancies and manual back-ups are still needed in case of infrastructure failure or natural disasters.

6. Conclusion

Malaysia's goals to adopt digital tools and technologies in the provision of public healthcare are laudable, and the government has made a decades-long effort to roll out an interoperable, nationwide EHR system. The Covid-19 pandemic showed that nationwide rollout and take-up is possible. Thus, the time is ripe for an integrated digital health records system that will be the bedrock for future healthcare and well-being management.

Such a system brings with it both benefits and challenges. Patient care can be improved; however, data governance is paramount to mitigate cybersecurity risks. A comparative analysis between Malaysia and four case study countries with varying healthcare delivery and digital health records systems highlights three specific areas for policy consideration.

First, patient inclusion and empowerment. Any digital health system has to be designed to be inclusive, regardless of patient location, demographics and digital literacy. Ideally, this system would also empower patients to increase their health literacy and better manage their own health.

Second, data governance. The nation needs appropriate data protection laws that make provision for digitally collected and stored private health data. Crisis management plans and complaints processes should also be developed and implemented. Patients and healthcare practitioners alike should be educated on their rights and responsibilities with respect to health data.

Third, system integration across the healthcare landscape and over the life course. Ideally digital health records should follow patients throughout their life course regardless of the sort of healthcare provision they seek and where they seek it. Responsible data sharing across facilities would enable comprehensive health data to be collected, in turn improving healthcare delivery and health outcomes.

MOH has the opportunity to build these principles into the design of its national digital health records system and ensure an agile and resilient system will be rolled out nationwide as planned.

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8. Appendices

8.1. EHR in other countries

Globally, countries such as Australia, China, Singapore and United States of America (USA) have leveraged digitalisation to improve healthcare efficiencies and patient-centricity[107]. More specifically, these countries have moved towards establishing EHRs as a foundational tool for digital transformation within the healthcare sector[108].

EHRs provide updated and detailed information about a patient's health that allows for easy coordination between healthcare providers across the healthcare landscape[109]. Past research has shown that EHRs are associated with greater compliance with clinical guidelines[110], effective care (e.g., waste reduction)[111], and reduced medical and medication errors[112] in addition to reducing costs[113]. Although medical errors stemming from reliance on EHRs have been cited in some research, they were largely attributed to poor system design and lack of user training and integration[114].

However, the implementation of each EHR system and the legislations that accompany it differ between countries such that each country's system has its definition of its role, purpose, standards, and operating guidelines. For example, Australia and Singapore both have centralised EHR systems that are implemented on a national scale whereas in China and the USA, a more decentralised approach has been taken, although perhaps to different degrees. The differences are summarised in Table A1 below and will be discussed further in this appendix.

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[107] Stephanie (2017b); Atherton (2011); Xu et al. (2013); Gao et al. (2013); Salleh, Abdullah, and Zakaria (2021)

[108] We note that the case study countries may not have achieved full EHR status however, the goal of this paper is to explore the methods of implementation to pinpoint best practices and key lessons.

[109] ONC (2022)

[110] Dexter et al. (2001); Willson et al. (1995)

[111] Chen et al. (2003)

[112] Bates et al. (1999); Devine et al. (2010); Bates et al. (1998)

[113] Agrawal (2002)

[114] Campbell et al. (2006); Koppel et al. (2005)

Table A1: Brief comparison between EHR systems

Measure	Australia	China	Singapore	USA
System Name	My Health Record (MHR)	Electronic Health Record (EHR)	National Electronic Health Records (NEHR)	Electronic Health Record (EHR)
Estimated cost of Implementation	USD1.4 billion (over 10 years)	USD19 billion (for overall development)	USD265 million (over 10 years)	N/A
Governance	Centralised	Decentralised	Centralised	Decentralised
Module Examples	e.g., Shared Health Summaries, discharge summaries, event summaries, pathology result reports and specialist letters	e.g., Personal information, disease and health summary, COVID-19 control and management	e.g., Admission and visit history, laboratory test results, radiology reports, medication history, history of surgeries, immunisation and allergies record	e.g., Medical history, diagnoses, medications, treatment plans, immunisation records, allergies, radiology images, laboratory and test results
Authority	Australia Digital Health Agency	National Health Commission	Integrated Health Information Systems	Office of the National Coordinator for Health Information Technology
Informed Consent	Mandatory	Mandatory	Mandatory	Depends on state privacy laws
Patient chooses who accesses their data	Yes	No	No	No
How patient accesses their data	myGov	Hospital app, WeChat and relevant third-party app	Health Hub	API-enabled app

Note: Estimated cost[115] for China is obtained from Gao et al. (2013). Cost for Singapore and Australia are proposed budget estimations for an implementation period between 2010 and 2020.
Sources: Liang et al. (2019); ONC (2014); Xu et al. (2013); My Health Record (2018); Integrated Health Information System (2019); MOH-PRC (2009)

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[115] Please note that throughout this paper all figures in AUD were converted to USD at a rate of about AUD1.00 to USD0.71; SGD were converted to USD at a rate of about SGD1.00 to USD0.73; CNY were converted to USD at a rate of about CNY1.00 to USD0.15, based on Google's Currency Converter on August 12, 2022.

8.2. Australia

Australia opted to roll out a centralised electronic health database, although Australia's system underwent a revamp after an initial series of state-level pilot testing. The original system, known as the Personally Controlled Electronic Health Records (PCEHR) system, was initially established in 2008 under the purview of the National E-health Strategy[116].

Built on an opt-in model, where patients had to volunteer to participate in the system, the PCEHR faced issues of low adoption[117]. This led to the adaptation of the system into an opt-out model where patients would be automatically registered into the system, although the autonomy to withdraw was retained[118].

The PCEHR system was also rebranded as the My Health Record (MHR) system, owned by the Australian Digital Health Agency (ADHA) and placed under the purview of the National Electronic Health Transition Authority (NEHTA)[119]. According to the Australian government, the MHR would allow both patients and health practitioners to access health information such as Shared Health Summaries, discharge summaries and pathology result reports[120].

Several platforms were set up to facilitate access to the MHR system such as the National Provider Portal and conformant clinical software for healthcare practitioners whereas patients could access and control their data through the online myGov portal[121].

In Australia, the My Health Records Act 2012 details that healthcare providers are not required to obtain consent to upload clinical information on MHR[122]. However, the My Health Records (Assisted Registration) Rule 2015 does require informed consent to be obtained from the patient for registration in the MHR system[123]. Nonetheless, Australia is the only country that allows patients to set restrictions on who can access their data and which documents can be viewed[124].

Between 2010 and 2020, the implementation of an EHR system was allocated a total of approximately AUD1.97 billion, equivalent to about USD1.4 billion, by the Australian government[125]. Based on the original parliamentary budget for PCEHR covering the period of 2010 to 2012 as seen in Table A2, the element that incurred the highest cost was the establishment of standards and infrastructural foundations[126].

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[116] Xu et al. (2013)
[117] McDonald (2012)
[118] Commonwealth of Australia (2017)
[119] Xu et al. (2013)
[120] Xu et al. (2013)
[121] My Health Record (2018)
[122] Gallagher (2018b); Commonwealth of Australia (2012)
[123] Commonwealth of Australia (2015)
[124] Integrated Health Information System (2019)
[125] Taylor and Corderoy (2020)
[126] Xu et al. (2013)

In 2017, the government announced an additional investment of AUD374.2 million for the expansion and continuation of the MHR project over the span of two years which included initiatives to increase private adoption and research quality as well as enhance data quality and security[127].

Table A2: Parliamentary budget breakdown of PCEHR

PCEHR Budget	2010-2011 (AUD in millions)	2011-2012 (AUD in millions)
Governance and Program Management	25.7	18.8
Adoption and Transition	42.0	56.8
Foundational Infrastructure	51.7	97.8
Architectural Framework	33.9	48.9
Operations	11.2	30.4
Contingency	16.9	25.6
Departmental expenditures	4.2	2.9
Total	**185.6**	**281.2**

Source: Commonwealth of Australia (2012)

8.3. China

In contrast, China's approach to EHR was through the implementation of a decentralised database designed by top-to-bottom policies and legislation under the authority of the National Health Commission[128]. The system consists of personal information, disease and health summaries as well as referral records and statutory hospital certificates and reports[129].

Following the announcement of its 11th Five Year Plan, China introduced a series of technical standards and policies[130] that gave structure to the construction of EHRs and EMRs by providing a comprehensive high-level design to the system[131]. As of 2021, 31 policies and 134 standards and guides related to digitalised health records had been released[132].

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[127] Commonwealth of Australia (Department of Health) (2017)

[128] Gao et al. (2013); Liang et al. (2019)

[129] Ministry of Health of the People's Republic of China (2011)

[130] State Council of China (2006)

[131] State Council of China (2006)

[132] Liang et al. (2021)

With the many policies and standards established since the 2000s, China set up the HISPC, which is responsible for the standardisation, administration, certification and promotion of health information technology.

An example of their initiatives is the "46312" Strategy, introduced with the goal of achieving integration and sharing of health information on the county, municipal, provincial and national levels[133]. Additionally, HISPC also provides certification for EHR systems that have met the requirements for interoperability and integration through testing and evaluation[134].

Since there is no national EHR system in place, healthcare providers utilise systems offered by individual EHR vendors. These vendors need to meet standards and requirements established by the government to ensure the interoperability and security of systems[135].

Digital health legislation[136] also requires informed consent to be obtained for data collection. Access to health records is granted to individuals through specific hospital apps, third-party apps or WeChat[137]. Access roles to patient data are outlined under the requirements of the Information Security Technology-Health and Medical Data Security Guide[138] as shown in Table A3. However, some important data catalogues are formulated by individual departments.

Table A3: Access levels and usage

Level	Usage	Risk	Example Modules Accessible
1	Public	Very low	Hospital name, address, phone number
2	Wide range access	Low	Non-identifiable Data for Authorised Research Purposes
3	Moderate range	Moderate	Data that has been partially de-identified but may still be identifiable, limited to authorised access
4	Small range	High	Identifiable data, only for medical personnel query
5	Limited range	Very high	Sensitive information such as AIDS and HIV, limited to main medical personnel that is heavily controlled and monitored

Source: Wu (2021)

Although the current integration level has only reached a regional level, there have been recent discussions on further enhancing interoperability through researching and constructing a national integrated and interoperable EHR system[139]. In terms of the cost, according to a 2013 review, it was estimated that the development of China's EHR system amounted to approximately

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[133] Yin (2014)

[134] Dong (2014); The State Council of The People's Republic of China (2019)

[135] Constitution of the People's Republic of China (2016b); (2016a)

[136] Constitution of the People's Republic of China (2014); Standing Committee of Shenzhen Municipal People's Congress (2021)

[137] Shu et al. (2021); Apple (n.d.)

[138] Wu (2021)

[139] Health Commission of Hebei Province (2022)

CNY130 billion, equivalent to USD19 billion. On the other hand, the general maintenance costs were estimated to be in a range of CNY65 billion to CNY260 billion[140]. To our knowledge, the exact budgetary allocations are not publicly available.

8.4. Singapore

Singapore's version of an EHR system is a government-owned centralised database known as the National Electronic Health Record (NEHR), developed by the Integrated Health Information System and owned by Singapore's MOH[141]. The NEHR consists of a set of longitudinal electronic care records comprising a patient's profile, admission and visit history, discharge summaries, radiology and laboratory tests, medication history, surgical history, immunisation records as well as their known allergies and adverse drug reactions[142].

Patients are able to access limited information in the NEHR database via a national online portal known as HealthHub[143]. However, access is only available to authorised healthcare professionals that are managing the patient's care and bounded by law and ethics. Employers, insurers and patients are not able to access NEHR. Access to NEHR for public health functions will require MOH's approval.

The NEHR served to reconnect and reduce inter-cluster competition that existed in the 2000s between the two major public health clusters, Singapore Health Services (SingHealth) and the National Healthcare Group (NHG)[144]. Officially rolled out in 2010, the implementation of the NEHR was conducted in two phases. The initial stages of the project were aimed at achieving direct data sharing through the NEHR portal whereas the goal of the second stage was to enhance data integration and flow through the establishment of bidirectional information flows.

Subsequently, patient access to personal health records was granted in 2015 through the launch of the HealthHub app[145]. Under Singapore's Personal Data Protection Bill 2020, organisations are required to obtain informed consent for any collection, use and disclosure of personal health data[146].

Over a 10-year period, the NEHR has been reported to have cost SGD200 million for the first phase and SGD163 million for the second phase[147]. Thus, the total estimated cost of Singapore's NEHR implementation between 2010 and 2020 would have been approximately SGD363 (USD265) million.

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[140] Gao et al. (2013)

[141] Stephanie (2017b)

[142] Integrated Health Information System (n.d.)

[143] Integrated Health Information System (n.d.)

[144] Stephanie (2017b)

[145] Integrated Health Information System (n.d.)

[146] Constitution of the Republic of Singapore (2020)

[147] Tan and Seng (2009); Ministry of Finance of Singapore (2021)

8.5. USA

The EHR system in the USA is decentralised and managed by ONC[148]. A patient's health record consists of modules such as medical history summaries, medication and treatment plans, immunisation and allergy records as well as laboratory and radiology results.

Initially used only by the Department of Veteran Affairs in the 1970s, EHRs were gradually introduced to the general public during the Bush administration with many efforts on adopting health information technologies nationwide occurring in the 2000s[149]. In 2004, ONC was established with the main objective of improving healthcare services and data exchange capabilities through health information technology developments[150]. However, the USA did not focus on rolling out a national EHR system and individual healthcare providers were allowed to adopt different systems at their own pace.

Thus, the USA adopted a certification approach, led by ONC, to ensure that integration, interoperability and standards were met by individual EHR systems as done in China[151]. Individual EHR vendors could certify their system by meeting the required criteria although the USA also introduced an incentive program that provided payments to healthcare providers for any "meaningful use[152]" of the EHR systems[153].

Additionally, EHR vendors are required to ensure interoperability through meeting Application Programming Interface (API) requirements to allow individuals to view their health data through an API-enabled app[154]. Unlike the countries previously described, HIPAA does not require healthcare providers in the USA to obtain informed consent for EHR sharing or transfer. However, health data sharing is subject to individual state laws and policies[155].

The estimated cost of implementation differs between the type of EHR that a hospital implements. That is, whether hospitals choose a web-based or on-site EHR deployment. The ONC estimated that the total cost for a five-year ownership period for a web-based EHR was around USD58,000 whereas the on-site deployment would cost around USD48,000 for the same time period[156].

The cost also varies depending on the different service providers, locations and functionalities embedded in each EHR system. For instance, a 2011 review estimated that the implementation

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[148] Atherton (2011)
[149] Atherton (2011)
[150] Atherton (2011)
[151] US Congress (2015)
[152] Meaningful use comprises three components (1) the ability to use EHR meaningfully; (2) utilising health information exchange to improve quality of care; (3) utilising EHRs to submit clinical quality measures with a minimum coverage of 50% of domains (i.e., patient and family engagement, safety, coordination, population and public health, efficiency of resources, clinical effectiveness)
[153] US Congress (2015)
[154] US Congress (2018)
[155] ONC (2019)
[156] ONC (2014)

cost, alongside a year's worth of maintenance fees, would be around USD247,000 in North Texas[157].

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[157] Fleming et al. (2011)