Digital interoperability

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Contents

What is digital interoperability?

Digital interoperability is the ability of different digital systems, applications, or devices to seamlessly exchange data and work together effectively, even if they are developed by different vendors or operate on different platforms.[i] Interoperability enables smooth communication and interaction between various components of digital ecosystems, facilitating collaboration, data sharing, and interoperable services.[ii] In healthcare, it enables information — such as patient data, diagnostic results (including pathology and radiology) — to be seamlessly transferred between people, organisations, and systems. This results in a connected healthcare eco-system that shares health information securely, safely, and without requiring specific effort from the people and organisations transmitting it.[iii]

To ensure we have a health system that is fit-for-purpose for the future — especially with the increasing use of digital records across a federated, fractured health system — a push toward digital interoperability and connectedness can help overcome information silos, enable more effective use of resources, and accelerate adoption among health practitioners and their patients. However, this potential can only be fully realised if barriers to interoperability, use, integration, and adoption can be overcome.

The current situation of interoperability in Australia

The history of health interoperability in Australia

The history of health interoperability in Australia has evolved over several decades, marked by efforts to improve the exchange of health information and enhance collaboration among healthcare providers and systems.

In the early 1990s, various states and territories in Australia began exploring electronic health record (EHR) systems and health information exchange (HIE) initiatives.[iv] Further to this, states and territories progressively updated their poisons regulations to allow for computer-generated prescription writing. This enabled MedicalDirector and Genie Solutions software to deliver computer prescribing to the general practice community.[v] Additionally, the National Health Information Agreement (NHIA) was established in 1993 as a collaborative effort between the federal, state, and territory governments to improve the collection and sharing of health data.[vi] This initiative laid the foundation for future interoperability initiatives by establishing principles for data standards and information management. In the late 1990s, the General Practice Strategy Review Group[vii] further promoted the computerisation of general practice. This resulted in the Australian Government funding the General Practice Computing Group,[viii] which saw computerisation incorporated into the Practice Incentive Program (PIP).[ix] This not only increased patient safety — as general practitioner information systems began to include patient history, including allergies and adverse drug reactions — but also generated cost savings through administrative efficiencies, adding momentum to the shift away from information silos.[x] Following this, the Australian Government announced MediConnet (2000) and HealthConnect (2004) programs[xi] to encourage the use of electronic communication to improve the safety and quality of health data. HealthConnect was a national program launched with the goal of establishing a national electronic health record system in Australia.[xii] It aimed to improve interoperability by creating a secure platform for sharing health information among healthcare providers and patients.[xiii] However, the program faced challenges, including technical issues and concerns about privacy and security.[xiv] In 2003, the Australian Health Ministers' Advisory Council (AHMAC) was tasked to create a national action plan for a collaborative federal, state, and territory funding body aimed at establishing a national e-health system.[xv] This resulted in the establishment of the National E-Health Transition Authority (NEHTA) in 2005,[xvi] which aimed to accelerate the adoption of a national electronic health information system. The outcome of this was the development of specifications, standards, and infrastructure, which were strongly endorsed by the Australian Medical Association (AMA) through its 2006 position statement on Safety and Quality of E-health Systems. Subsequently, a common language for health communications was established, along with the creation of unique healthcare identification numbers for all individuals, providers, and organisations.[xvii] This initiative was endorsed by the AHMAC as part of the National E-health Strategy in 2008.[xviii]

In 2012, the Australian Government launched the opt-in *Personally Controlled Electronic Health Records Act 2012* (PCEHR).[xix] The aim was to engage patients and carers in the digital health journey, as this system could contain clinical documents, test results, information added by the individual, as well as Medicare, the Pharmaceutical Benefits Scheme (PBS), and immunisation data.[xx] Due to a lack of consumer usage, a review of the PCEHR system was announced, with the findings Review of the Personally Controlled Electronic Health Record released in May 2014. The review determined there was "overwhelming support" for the development of an electronic health record

system, however, it concluded a "change in approach" was required to overcome implementation issues and "to review the strategy and role that a shared electronic health record plays in a broader system of health care".[xxi] In 2015, the *Health Legislation Amendment (eHealth) Act 2015* was passed. This legislation renamed the PCEHR Act to the My Health Record Act and rebranded 'consumers' in the legislation as 'healthcare recipients' under an opt-out model, which meant all Australians were automatically included, unless they deliberately chose to opt-out.[xxii,xxiii] This expansion aimed to improve interoperability and co-ordination of care by providing a more comprehensive and accessible health record for patients and healthcare providers.

In 2016, the Australian Government established the Australian Digital Health Agency (ADHA) to lead and co-ordinate national digital health initiatives, including interoperability efforts.[xxiv] In 2017, the National Digital Health Strategy was released, which identified interoperability as a priority. In 2023, the ADHA published the Connecting Australian Healthcare Interoperability Plan for 2023–2028, outlining a national vision to share consumer health information in a safe, secure, and seamless manner across five priority areas relating to identity, standards, information sharing, innovation, and measuring benefits.[xxv]

Various standards and frameworks have been developed to promote interoperability in the Australian healthcare sector. These include standards for data exchange, for example, Health Level 7 (HL7), Systemized Nomenclature of Medicine — Clinical Terms (SNOMED CT), privacy and security, the *Personally Controlled Electronic Health Records Act 2012*, and clinical terminology. While progress has been made in advancing health interoperability in Australia, challenges remain. Currently, only one in 10 medical specialists use My Health Record and only one in five diagnostic imaging reports are uploaded[xxvi] due to inefficiencies and incompatibilities between the My Health Record system and health IT software, such as Best Practice. Beyond this, there are instances where different departments within a hospital are using software which is incompatible with other departments. In an extreme example, clinical notes taken in the emergency department must be printed off and physically carried to other departments, including the intensive care unit (ICU), where these notes are then re-typed into the ICU software.

This situation not only creates double-handling of patient notes and the duplication of work and resources, but it also causes unnecessary delays between diagnosis and treatment. Additionally, it increases the likelihood of information being lost or misplaced and the occurrence of errors during data entry. Issues such as software incompatibility stem from the absence of a legislated authority to enforce interoperability standards, including data-sharing protocols between different software programs. This situation is the primary barrier to an effective interoperable healthcare system in Australia. Specifically, the absence of political mechanisms necessary to enforce compliance with a set of agreed-upon legislated national standards by all involved parties remains the greatest hindrance to achieving health interoperability in the country. As a result, establishing and enforcing the adoption of national health IT standards for patient healthcare data — both for software providers and users — should be at the forefront of efforts to implement an effective interoperable health system nationwide.

Australia's global position of health interoperability

Australia strongly supports interoperability of healthcare software and clinical information systems. The Australian Government has recognised the importance of interoperable health systems in improving healthcare delivery, patient outcomes, and overall efficiency within the healthcare sector.

The past decade has seen the establishment of a plethora of committees and agencies, whose sole purpose is to investigate data interoperability and the necessary steps to achieve it in the healthcare sector. This was first seen in 2016, when the Public Governance, Performance and Accountability Rule established the Australian Digital Health Agency (ADHA) in law[xxvii] — a statutory agency responsible for My Health Record and the digitalisation of Australia's healthcare system.[xxviii] The ADHA aims to improve the accessibility, quality, and efficiency of healthcare through digital technologies. The central theme of the strategy is interoperability, with a focus on enabling the seamless exchange of health information across different systems and clinical settings. Furthermore, the agency also addresses aspects of healthcare digitalisation, including electronic prescriptions, health referral systems, and other e-health programs in line with the National Digital Health Strategy.[xxix] Beyond this, the Council for Connected Care — established in 2023 as a result of the Strengthening Medicare Taskforce Report — aims to facilitate and support the implementation of the Connecting Australian Healthcare — National Healthcare Interoperability Plan 2023–2028. The Australian Digital Health Standards advisory group also provides advice to the Council for Connected Care on digital health standards.

Following the establishment of the ADHA, the need for stringent standards and national conformance agreements for digital infrastructure — ensuring the unification of information across the healthcare sector — was recognised. According to the ADHA, standardisation refers to "*the processes via which specified domains (e.g. the public and private health sectors) achieve a targeted level of consistent implementation of specific standards, to achieve a defined purpose".*[xxx] In this regard, standards are defined as " ".[xxxi] As a result, in 2022, the ADHA signed a Memorandum of Understanding (MOU) with the not-for-profit standards developing organisation [Health Level Seven Australia Ltd (HL7)](#) to support the robust development and implementation of digital health standards and specifications — such as the [Fast Healthcare Interoperability Resources (FHIR) Specification)](#) — to enhance connectivity across the national healthcare system.[xxxii] Through these actions, Australia aims at supporting the development and implementation of interoperability standards to promote consistency and compatibility in health information exchange. Furthermore, Australia has implemented a Healthcare Identifiers Service (HI Service), which assigns unique identifiers to individuals, healthcare providers, and organisations involved in the delivery of healthcare services. These identifiers help facilitate the accurate and secure exchange of health information across different systems and care settings.[xxxiii]

In 2023, the ADHA launched the [National Healthcare Interoperability Plan for 2023–2028](#), mapping out a pathway to a more interoperable Australian health system and supporting the implementation of digitally enabled models of care. The vision of the [2023–28 National Digital Health Strategy](#) is for digital health to transform the way Australians manage their own health and wellbeing, as well as how they access healthcare, leading to better outcomes for all. The strategy identifies interoperability as a key change enabler.[xxxiv] Beyond this, it defines a shared vision for long-term interoperability in the Australian healthcare environment, as well as exploring current barriers and enablers to interoperability. It recommends priority actions across government, the health technology sector and private health organisations to increase interoperability and improve workflows, accessibility, and outcomes within the healthcare sector. The plan identifies five priority areas to advance digital health interoperability in Australia — identity, standards, information sharing, innovation, and benefits.[xxxv]

In June 2023, the [Data and Digital Ministers Meeting (DDMM)](#) announced the release of the [National Strategy for Identity Resilience](#), which was developed in close collaboration with the federal government, as well as state and territory agencies.[xxxvi] The purpose of the strategy is to demonstrate the commitment of all Australian governments to strengthening identity infrastructure and building resilient identities that are hard to steal, but if compromised, easy to restore.[xxxvii] Following this, in July 2023, the federal, state, and territory governments signed the [Intergovernmental Agreement on National Digital Health 2023-2027](#) to enable interoperability and connected data across Australia's healthcare settings. This agreement aims to support high-quality patient care and improve the efficiency and sustainability of the healthcare system,[xxxviii] further reinforcing Australia's commitment to data interoperability as a priority in healthcare.

Why is digital interoperability important?

Medical data today lacks digital interoperability, as most healthcare data is stored in isolated databases, incompatible systems, and proprietary software. This fragmentation prolongs the time doctors need to access crucial patient information at the point of care.[xxxix] This significantly impacts the efficiency of healthcare delivery, slowing medical progress for both patients and doctors. Beyond enabling instant access to critical patient information, digital interoperability can generate new medical insights, allowing existing data sources to be analysed more efficiently.[xl] This can accelerate translational medicine, helping to move research discoveries swiftly from the laboratory to the point of care.[xli] On a larger scale, it can drive evidence-based practices in medicine and accelerate their implementation into public health policies.[xlii] To meet the emerging challenges of Australia's ageing population, changing disease patterns, increasingly complex healthcare requirements, and the need to deploy scarce resources efficiently, our health systems need to fundamentally transform the way they use available data.[xliii] The most efficient way to do this is to employ interoperable data formats and infrastructure across the healthcare sector.[xliv] This will not only improve the lives of patients, doctors, and all healthcare professionals, but the quality of the entire health system, resulting in a more effective, productive, and sustainable health system.

Under the ADHA's National Digital Health Strategy, four change enablers have been identified:

1) **Policy and regulatory settings** that cultivate digital health adoption, usage, and innovation.
2) **Secure, fit-for-purpose, and connected digital solutions** that support interoperability.
3) **A digitally ready and enabled health and wellbeing workforce** equipped with the necessary tools.
4) **Informed, confident consumers and carers** with strong digital health literacy.

As outlined by the ADHA, data interoperability is expected to benefit four specific categories: 1) patient experience, 2) safety, 3) productivity, and 4) reduced costs. Additionally, it aims to enhance data for research and practice.[xlv] A synopsis of the benefits within these categories is provided below.

1. Patient experience

Throughout a whole-of-life healthcare journey, multiple healthcare providers interact with a patient at various times, often across different locations across Australia or even overseas. An interoperable healthcare system would allow providers to access all of the patient's information — including their history, diagnoses, and medication list — in real time, enabling them to deliver high-quality and safe care, while improving the patient's overall experience. For example, if a patient seeks treatment at a healthcare service they have not attended before, a doctor at the treating site, using an interoperable healthcare system, could instantly and completely access the patient's records. Having access to the patient's complete medical history enhances patient management by improving the speed and accuracy of diagnosis and subsequent treatment delivery. In Australia, interoperability is particularly important, as it enables health data to be readily accessed and exchanged across state borders, including in the most isolated remote communities, where access to medical specialists is either non-existent or limited. This system will ensure all doctors are fully informed of a patient's care needs, facilitating open communication between medical providers and patients. Nationwide interoperability helps prevent delays in retrieving prior medical information and reduces the need to duplicate diagnostic imaging (radiology) and pathology tests. Beyond the quicker delivery of care through instant access to patient medical records, data interoperability in health IT would enhance patient engagement by empowering individuals as active participants in their own care. It encourages them to take part in shared decision-making regarding their health.

The development of data interoperability and electronic health records (EHRs) would enable patients to easily access their information and permit actions such as the scheduling of appointments from anywhere in the world. This newfound accessibility enables patients to make informed decisions about their care, while also making it easier for providers to collaborate on treatment plans and improve them.[xlvi] Beyond improving patient experience, data interoperability can enhance follow-up care for missed appointments, consultations, and diagnostic testing. In this scenario, a healthcare provider can search for specific patient cohorts within a practice to monitor and strengthen adherence to healthcare regimens, such as mammograms or routine blood tests.[xlvii] In this way, a connected healthcare system improves the patient experience by enabling more effective communication and enhanced collaboration between doctors, other medical providers, and patients for their whole-of-life health journey. This not only reduces time wasted by everyone involved but also minimises resource inefficiencies. For example, medical investigations can be accessed by all who require them, whenever they need them, without the need for double handling.

2. Safety

At its simplest, health interoperability would improve patient safety through the use of wearable patient safety devices, which, upon activation, could automatically alert your general practitioner (GP) if it detects something is wrong. Additionally, health interoperability would enable easy access to appointment reminders, better tracking and reporting of consultations, as well as diagnostic testing, clinical decision support, and the availability of patient data, allowing for better monitoring of patient care. When evaluating patient devices and monitoring systems, it is crucial to consider their medico-legal and financial implications. Given the rapid advancements in this field, these implications must be continuously reviewed and evolved to remain aligned with the pace of technological progress. Health interoperability can reduce the risk of medical errors through the real-time provision of patient medical history, medications, drug adversities and allergies, and other important patient information. A 2022 study on *The Impact of Electronic Health Record Interoperability on Safety and Quality of Care in High-Income Countries* found EHRs positively influenced medication safety, while reducing the risk of data errors, patient safety events and costs,[xlviii] by streamlining administrative processes. A further study found the quality of medical data capture and information

management in patient medical records varied across hospitals, with some hospitals exhibiting very poor documentation and recording-keeping of patient histories. The study found only 49 per cent of audited records showed evidence that discharge summaries were sent outside the specific hospital. It recommended medical history documentation guidelines and standardised discharges summaries be implemented in Australian healthcare services to improve quality and continuity of care.[xlix]

Due to the sensitive nature of healthcare data, ensuring patient privacy and data security is paramount. As a result, concerns about data breaches and unauthorised access are the main obstacles to achieving interoperability. These concerns include the use of portable devices that are not password protected, which could make patient records vulnerable to invasion of privacy, highlighting the importance of data governance.[l] For the purpose of this report, data governance is defined as a documented set of processes, policies, standards, and responsibilities that ensure the effective and efficient use of health data. Effective data governance frameworks guarantee the quality, security, and privacy of the patient data that is collected, stored, and shared.

The AMA supports governance frameworks that have clearly identified and stated data governance roles within relevant entities. These frameworks should specify who can access data, under what circumstances, for what purposes, and how the data can be accessed. Healthcare entities that collect and store patient data must ensure there is a single source of truth — a single data repository — so that data is easy to find, access, use, and share, while adhering to relevant data safety and privacy principles. Appropriate data governance should enable and ensure the protection of data integrity, preventing unauthorised access, data loss, modification, or deletion. Governance frameworks must ensure that all data use and requests for data sharing demonstrable tangible value in improving the healthcare system as a whole. Furthermore, data governance frameworks applied by relevant entities in the healthcare space must ensure patient data is handled in a transparent and accountable manner, with robust privacy protections in place. These governance principles would guarantee the quality, security, and privacy of patient data, fostering a connected, interoperable healthcare system based on the principles of data safety, quality, privacy, and portability.

3. Productivity and cost

Interoperability will enable healthcare providers to access data from different systems in an optimised manner, streamlining administrative processes, eliminating redundant data entry, reducing paperwork, and increasing productivity by minimising the administrative burden. A recent time-allocation study found that, on average, physicians in the United States spend 45 per cent of their day on administrative tasks such as EHR and desk work, and only 27 per cent providing care to patients in their offices.[li] Interoperability will eliminate the need for redundant data entry across multiple health software interfaces, allowing medical practitioners to focus solely on patient care, rather than administrative tasks. Beyond this, interoperability will not only save time but also reduce costs and resource usage. Doctors have reported spending half their time searching for patient information, and when test results cannot be found, they often resort to ordering new ones — even though they know the tests have already been performed.[lii]

Furthermore, information systems that operate in isolation are more likely to contain redundant or misleading information, compromising the overall quality of data and its interpretation among different healthcare providers. By synchronising interoperable data systems, the quality of data is enhanced, and sources of information can be integrated, creating a more cohesive data set. This not only improves data accuracy and interpretation but also reduces the risk of misinformation.

4. Practice and research

Beyond improving healthcare at the point of care, data interoperability can also advance medical research. In general, structuring high-dimensional health data according to national standards makes it much easier to analyse by reducing the effort required for data cleaning and pre-processing. This not only streamlines research processes but also allows the development of analysis scripts — necessary for the analysis of high-dimensional data — to be more flexible and accessible.[liii] Additionally, data interoperability ensures a single analysis can be conducted across many different data sources, encompassing data from various institutions or countries. This enables research in areas where data is sparse and needs to be pooled across different institutions, facilitating more robust analyses and improving the quality of data.

Interoperable information formats, particularly for patient data, open various opportunities for research, including large-scale observational studies at regional, national, and international levels. Such analyses can address public health concerns and epidemiological questions by providing up-to-date insights into the prevalence and incidence of diseases, enabling better tracking, monitoring, and response efforts — minimising the risk of epidemics escalating into pandemics. The interoperability of real-world data also creates opportunities for Artificial Intelligence (AI) and machine learning methods to identify patterns and correlations in high-dimensional datasets. This allows researchers to identify new research questions and areas of study, which can subsequently be investigated through controlled clinical trials.

One of the key barriers to advancing medical research is the difficulty in identifying sufficient participants for robust clinical trials. Data interoperability would enable patient information for clinical trials to be stored in databases with sharing capabilities, allowing deidentified data to be accessed and shared for research purposes.

Provided all privacy protection requirements are met and patient consent has been obtained for data sharing or research use, researchers could more easily identify experimental cohorts of patients with specific medical traits and conditions qualifying them for clinical trial participation. For example, data interoperability could facilitate the identification of all patients with the BRACA1 gene mutation, and, with input from machine learning tools, assess their suitability for clinical trial participation. This would advance the development of effective treatments by improving the efficacy of medical research through interoperable systems.

Benefits to key stakeholders

Individuals

Interoperability in healthcare offers significant benefits to individuals, empowering them with greater control over their health information and enhancing their overall experience. Specifically, health interoperability would enable individuals to easily access their secure health data, fostering greater patient engagement and control. Furthermore, interoperability allows individuals to gain a comprehensive view of their health information, aggregated from various sources such as hospitals, clinics, pharmacies, laboratories, and wearable devices. This comprehensive view empowers individuals to make more informed decisions about their health and healthcare options.
Digital health technologies are poised to significantly impact elderly patients, especially as the population ages and the demand for healthcare increases. Elderly patients, especially those in aged care, stand to gain substantial benefits from enhanced interoperability. This is particularly crucial as dementia becomes a leading cause of disease and death in Australia.[liv] Patients with dementia often struggle to compile and communicate their healthcare information effectively across the healthcare system. Digital health tools, such as electronic health records (EHRs) and telehealth services, can bridge this gap by ensuring seamless information sharing among healthcare providers. This not only improves the co-ordination of care but also reduces the burden on patients and their caregivers. Moreover, digital health solutions can provide real-time monitoring and aid in the delivery of personalised care plans, which are essential for managing chronic conditions and preventing complications. By leveraging these technologies, the healthcare system can better address the unique needs of elderly patients, ultimately enhancing their quality of life and improving health outcomes.

Similarly, digital health can support other large groups of patients who face challenges in managing and communicating their healthcare information and accessing the healthcare system. These groups include, but are not limited to, patients with severe mental health conditions, including addiction issues, individuals with traumatic brain injuries such as stroke, and culturally marginalised communities. Lower socioeconomic groups, which are often overrepresented in terms of healthcare needs, can struggle to access the healthcare system and effectively compile, communicate, and co-ordinate their care. Digital health technologies, through enhanced interoperability, can significantly alleviate these challenges by ensuring seamless information sharing and improving access to care. This can lead to better health outcomes and more equitable healthcare delivery for vulnerable populations, ultimately bridging gaps in the healthcare system and providing essential support to those who need it most.

Healthcare providers

Healthcare interoperability will provide all healthcare workers with instant access to vital patient information in a format that is easy to understand, interpret, and act upon. For example, interoperability has the potential to monitor patient vital signs through a wearable device, which instantly redirects patient data to a monitoring device used by the treating doctor.[lv] Furthermore, this technology can immediately alert the treating provider if a problem is detected with the patient's vital signals.[lvi] This technology is already being rolled out in various digital hospitals around the world, including Queensland.[lvii] This interoperable technology not only improves patient care by instantly detecting medical episodes, but it also reduces the likelihood of further complications and the need for additional medical interventions.

Moreover, continuous patient monitoring reduces medical documentation and the administration workload for doctors, allowing more time for patient care. Furthermore, with interoperable health systems, healthcare providers can seamlessly share patient information across different care settings and specialties, enabling timely co-ordination of care and reducing the likelihood of medical errors.

Healthcare provider organisations

Health interoperability would enable healthcare provider organisations to safely share information across the entire healthcare system, supporting best-practice processes and new digital models of care. Specifically, data interoperability would reduce the need for duplicate medical tests and procedures by enabling healthcare providers to access and share relevant medical information. This not only saves time and resources but also minimises a patient's unnecessary exposure to radiation and other risks associated with medical interventions.

Funding organisations and regulators

Health interoperability would provide improved and up-to-date information to inform policy, thereby promoting funding and regulatory decisions that support high-quality care and best-practice regulation.

Health technology providers

Digital health interoperability would provide clear direction for health technology providers, enabling integration into forward workplans and improving access to standards and associated resources.

Overall, interoperability enhances an individual's ability to actively engage in their healthcare journey, facilitates better communication and collaboration among healthcare providers, and ultimately leads to improved health outcomes and greater satisfaction with the healthcare system.

What levers are necessary to achieve digital interoperability in Australia?

While the establishment of government agencies and the negotiation of agreements across the Australian healthcare system — including the Intergovernmental Agreement — are necessary steps in achieving interoperability, there are currently no well-defined regulations in place to achieve full healthcare digital interoperability. Without a nationally agreed regulatory framework with defined regulations and standards — re-enforced and mandated by legislation — the promised benefits of interoperability will never be realised. Achieving digital interoperability in the health sector requires a combination of technical standards, enforceable regulatory frameworks, incentives, and collaborative efforts across various stakeholders. Without the co-operation and collaboration of various bodies, achieving digital interoperability in the Australian health system will not be possible.

The initial requirement is for the Australian Government to establish and enforce regulatory frameworks. Specifically, the Australian Government needs to set clear regulatory guidelines for health data interoperability, which include mandates for data standards, privacy protections, security measures, and data sharing protocols. For example, while Australia has signed a Memorandum of Understanding with Health Level Seven Australia (HL7) FHIR

(Fast Healthcare Interoperability Resources),[lviii] and all states and territories have signed the Intergovernmental Agreement on National Digital Health 2023–2027[lix], there are still no political mechanisms to enforce these commitments. While ADHA and CSIRO are jointly leading the SPARKED FHIR Accelerator to co-design and deliver national, community-driven digital health interoperability standards — such as AU Core and clinical data models — to ensure consistent, secure and seamless health information exchange across Australia, these initiatives are slow. The government should endorse and mandate the use of these specific interoperability standards across the Australian healthcare sector. Such standardisations enable seamless data exchange and compatibility across different systems, IT software products, networks, and platforms, including secure and encrypted health messaging systems.

To achieve this, regulatory bodies need to collaborate with industry experts to develop and enforce these standards effectively. In the United States, these mandates are contained in the 21st Century Cures Act which also mandates data sharing standards.[lx] It would benefit Australia to also develop and enforce clear guidelines and expectations in relation to health interoperability. While Australia has voluntary codes in the digital health space, for example, the MSIA AI Governance Code, announced in December 2025, Australia should have mandated standards to realise the potential of interoperability. Having clear interoperability standards creates a level playing field for all relevant stakeholders, creating a fair marketplace for all parties.

The next action required is the passage of legislation establishing interoperability standards in Australia. The government should legislate that healthcare providers, electronic health record (EHR) vendors, health IT software providers, and other relevant entities adhere to the health interoperability standards, as discussed above. This would enhance accessibility to medical imaging and reports that have been previously performed across different providers, ultimately improving patient care. Furthermore, legislation should prescribe penalties for non-compliance with published interoperability standards. Such legislation should also contain clauses outlining the procedures to be implemented when circumstances change — for instance, when health systems and software require updates or modifications to adapt to the evolving landscape — and software providers fail to comply.

These penalties should be similar to those outlined in the 21st Century Cures Act and the EU Data Act, and should include significant monetary penalties, loss or restriction of software licence, and the removal from government contracts. To further support this, the Australia Government could establish certification programs to verify that healthcare IT systems and software comply with interoperability standards and security requirements. Certification would help streamline procurement processes and assure stakeholders of product quality, while the absence of certification would indicate non-compliance with health IT standards. The monitoring of compliance should fall under a single entity, such as the ADHA.

Clear legislation promotes transparency in pricing — for both software developers and their products — as well as penalties for non-compliance. It also fosters clarity in data sharing practices and incentivises data exchange. Additionally, to achieve health digital interoperability in Australia, strong data protection laws need to be legislated. These laws are crucial for building trust among patients and healthcare providers The Australian Government needs to ensure interoperability efforts comply with prescribed data protection regulation. The United States government ensures interoperability efforts and data protection comply with the Health Insurance Portability and Accountability Act (HIPPA). Similarly, the European Union has its General Data Protection Regulation (GDPR). Australia should adopt a similar approach when legislating for digital interoperability in healthcare.

To facilitate this transition, the Australian Government could offer financial incentives, grants, or tax benefits to encourage healthcare organisations — including public hospitals and general practices — to adopt interoperable systems from health IT vendors and companies and share health data using them. These benefits, including funding, could support infrastructure development, training programs, and implementation efforts. Collaboration among government agencies, healthcare providers, technology companies, and standards-monitoring organisations is essential for driving health interoperability initiatives forward.

Finally, the Australia Government could launch public awareness campaigns to educate patients, healthcare professionals, and policymakers on the benefits of data interoperability in the Australian healthcare setting. These campaigns could use traditional forms of communication and social media while identifying influential champions to promote interoperability. Additionally, they could conduct experiments in various healthcare settings, such as

hospitals, general practices and other health systems. By increasing understanding, these initiatives can foster support for interoperability initiatives and encourage active participation.

By employing these political levers in a co-ordinated manner, governments — both federal and state/territory — can create an environment conducive to achieving widespread health digital interoperability in Australia, ultimately leading to improved healthcare delivery, better patient outcomes, and increased innovation in the healthcare sector.

The promise of digital interoperability has the potential to create a single digital portal, enabling patients to access their complete medical records, history, prescriptions, reports, appointment reminders, and other essential medical information. This portal would also allow treating doctors to triage interventions and design personal healthcare plans, seamlessly integrating— general practitioners, pharmacies, allied health providers, and mental health services.

International best practice of policy tools

21st Century Cures Act

The 21st Century Cures Act, signed into law in December 2016, is a significant piece of legislation in the United States aimed at accelerating the discovery, development, and delivery of new medical treatments and technologies. While it primarily focuses on healthcare innovation, it also includes provisions related to digital interoperability, particularly in the context of electronic health records (EHRs) and healthcare information technology (IT) systems. This Act requires healthcare software vendors to upgrade their technology to a common set of modern, cloud-based healthcare data-sharing standards that are accessible to medical practitioners.

The 21st Century Cures Act includes provisions to promote greater access, exchange, and use of health information among different healthcare providers and systems. In the United States, FHIR has gained substantial momentum – with many EHR vendors and many healthcare providers support data exchange using FHIR-based application programming interfaces (APIs), driven by federal interoperability mandates.[lxi] One of the central provisions of the Act is the prohibition of information blocking, which refers to practices by healthcare providers, IT developers, health information exchanges (HIEs), and other entities that unreasonably limit the availability, exchange, or use of electronic health information. The Act empowers the United States Department of Health and Human Services (HHS) to identify and penalise entities engaged in such practices.[lxii]

Specifically, Section 4002 of the Cures Act requires that health IT developers, as a Condition and Maintenance of Certification requirement under the program, refrain from any actions that constitute information blocking, as defined in section 3022(a) of the Public Health Service Act (PHSA). As finalised, the Condition of Certification prohibits any health IT developer under the program from engaging in information blocking as defined by section 3022(a) of the PHSA. If found in violation, they may lose their federal certification status. Additionally, healthcare providers who engage in information blocking may be subject to "appropriate disincentives" as determined by the HHS.[lxiii]

Therefore, if vendors and software providers fail to meet these requirements, they may be seen as engaging in 'data blocking'. the legal ramifications include the possibility of jail time or significant monetary penalties — up to $US1 million per violation — and the loss of their federal certification status.[lxiv]

The Act requires certified EHR systems to support the use of APIs without special effort.[lxv] This provision aims to enable patients to access their health information through third-party applications of their choice, enhancing greater interoperability and data portability. In the United States, the government gave software providers five years — from 2016 until April 2021 — to comply with the mandated data-sharing standards.[lxvi]

The legislation mandates the establishment of a certification program for health IT developers to ensure their products meet certain criteria for interoperability, security, and usability. This program is overseen by the Office of the National Coordinator for Health Information Technology (ONC).[lxvii] The Act directs the ONC to develop and

implement standards and specifications for the secure exchange of health information, including guidelines for data elements, data formats, and APIs.

Importantly, if health IT software developers fail to comply with the requirements of the 21st Century Cures Act — particularly regarding digital interoperability and information blocking — they face various consequences.

These include:

1. **Penalties and enforcement actions**: The United States Department of Health and Human Services (HHS), through its Office of the National Coordinator for Health Information Technology (ONC), has the authority to investigate complaints and take enforcement actions against entities engaged in information blocking. Penalties may include fines and other sanctions of up to $US 1 million per violation.[lxviii]

2. **Exclusion from federal programs**: Non-compliant IT software developers may risk exclusion from participation in federal healthcare programs, such as Medicare and Medicaid. This could have significant financial implications for developers whose products are widely used in the healthcare industry.

3. **Loss of certification**: Developers of electronic health record (EHR) systems and other health IT products must obtain certification from the ONC to demonstrate compliance with interoperability standards and other requirements. Failure to comply with certification requirements could result in the loss of certification, making the product ineligible for use by healthcare providers participating in federal programs.

4. **Reputational damage**: Violations of the 21st Century Cures Act and related regulations could lead to reputational damage for IT software developers. Healthcare providers and organisations may be less inclined to purchase or use products from developers with a history of non-compliance or information blocking practices.

5. **Legal liability**: Non-compliance with the 21st Century Cures Act may also expose IT software developers to legal liability, including civil lawsuits from affected parties, such as healthcare providers, patients, or government agencies. This could result in monetary damages, legal fees, and other costs associated with litigation.

The Cures Act has driven the issue of healthcare interoperability to the forefront of the industry's agenda in the United States. With the mandate for EHR systems to adopt standardised APIs and the strict penalties for non-compliance and information blocking, healthcare providers are required to implement interoperability to ensure the efficient exchange of patient data, legal compliance, and the delivery of high-quality healthcare services.

EU Data Act

In November 2023, the European Parliament adopted the EU Data Act,[lxix] a new regulation providing harmonised rules on access to data — including patient health data — switching cloud providers, and interoperability requirements across the European Union. The Act specifically clarifies who can use what data and under which conditions.

The Data Act mandates that connected products and related services be designed to ensure that product and related service data is accessible by default. It will take effect 32 months after its passage through the European Parliament. The Data Act outlines interoperability standards for providers of cloud and other data processing services to facilitate compatibility.

Under the Act, to facilitate interoperability and the switching between data processing services, users and providers should consider the use of implementation and compliance tools — particularly those published by the European Commission, such as the EU Cloud Rulebook and guidance on public procurement of data processing services. In particular, standard contractual clauses are beneficial because:

i) they increase confidence in data processing services

ii) create a more balanced relationship between users and providers of data processing services

iii) improve legal certainty regarding the conditions that apply for switching to other data processing services.

In this context, users and providers of data processing services should consider using standard 'smart' contractual clauses or other self-regulatory compliance tools, provided they fully comply with this regulation and are developed by relevant bodies or expert groups established under Union law. Under the Act:

"the notion of a 'smart contract' … is technologically neutral. Smart contracts can, for example, be connected to an electronic ledger. The essential requirements should apply only to the vendors of smart contracts, although not where they develop smart contracts in-house exclusively for internal use. The essential requirement to ensure that smart contracts can be interrupted and terminated implies mutual consent by the parties to the data sharing agreement. The applicability of the relevant rules of civil, contractual and consumer protection law to data sharing agreements remains or should remain unaffected by the use of smart contracts for the automated execution of such agreements." [lxx]

In this way, health software providers cannot terminate or renege on an agreement — for example, data blocking — without mutual consent between the provider and relevant medical service agents.

The EU Data Act also stresses the need for European-wide standards for digital architecture:

"The [European] Commission should assess barriers to interoperability and prioritise standardisation needs, on the basis of which it may request one or more European standardisation organisations, pursuant to Regulation (EU) No 1025/2012, to draft harmonised standards which satisfy the essential requirements laid down in this Regulation." [lxxi]

In alignment with the United States, which has a national regulatory body to monitor compliance, the EU Data Act requires:

"*each Member State shall designate one or more competent authorities to be responsible for the application and enforcement of this Regulation (competent authorities)."* "*Member States shall ensure that the tasks and powers of the competent authorities are clearly defined and include: imposing effective, proportionate, and dissuasive financial penalties which may include periodic penalties and penalties with retroactive effect or initiating legal proceedings for the imposition of fines."* This regulation separates the body that defines standards from the body that enforces compliance with these standards.

"An entity falling within the scope of this Regulation that makes connected products available or offers services in the Union, shall be considered to be under the competence of the Member State in which its legal representative is located. Any competent authority may exercise its competence, including by imposing effective, proportionate, and dissuasive penalties, provided that the entity is not subject to enforcement proceedings under this Regulation regarding the same facts by another competent authority." [lxxii]

In this way, health software providers must adhere to interoperability standards set by the government within a specified timeframe. Failure to comply may result in substantial penalties.

What is Australia doing?

Australia is adopting a risk-based approach to mitigating potential threats, including the creation of new laws to regulate the use of artificial intelligence (AI) in high-risk settings, such as law enforcement, healthcare, and education. Under the government's proposal, an advisory body will work with industry experts to develop these laws and define what constitutes a high-risk system. The former Minister for Industry and Science, Ed Husic, had stated that new mandatory guidelines will help promote transparency regarding how designers develop AI models and will help keep users accountable. [lxxiii]

In November 2023, Australia attended the AI Safety Summit in the United Kingdom, and joined the European Union, along with 27 other countries, in signing the Bletchley Declaration. This commitment fosters international

collaboration on AI safety testing and the development of risk-based frameworks across nations to ensure AI safety and transparency.[lxxiv]

The Australian Government's interim response to the s*afe and responsible AI* consultation, held in 2023, by the Department of Industry, Science and Resources, stated the "government is already undertaking work to strengthen existing laws in areas that will help to address known harms with AI". The report, published in January 2024, states this work will include the implementation of privacy law reforms, a review of the *Online Safety Act 2021*, and the introduction of new laws relating to misinformation and disinformation.[lxxv]

In November 2023, the Australia Government announced the 2023–2030 Australian Cyber Security Strategy, a roadmap designed to help its vision of becoming a world leader in cyber security by 2030. Through the strategy, the government seeks to improve cyber security, manage cyber risks, and better support citizens and Australian businesses in navigating the cyber environment around them using six cyber shields.[lxxvi]

The 2023 Budget saw the Australian Government investing $951.2 million over four years in digital health technologies to build a more efficient, connected, and collaborative healthcare system. In particular, $325.7 million was invested to make the Australian Digital Health Agency an ongoing entity to deliver on the government's commitment to strengthening Medicare.[lxxvii] Beyond this, a further $429 million was invested into My Health Record to improve its compatibility with widely used information and billing systems to aid in connecting the health system, so patients can access and securely share their personal data.[lxxviii] Finally, $126.8 million was invested to renew the Intergovernmental Agreement on National Digital Health for four years to progress the secure, safe and effective sharing of patient data across the Australia health system. Further to this, the 2023–24 Australian budget announced the Australian Government is investing $19.7 million over four years through the Department of Health, Disability and Ageing and Aged Care to support the rollout of MyMedicare; a voluntary patient registration model aimed to provide better care for people who choose to register with their general practice and nominated general practitioner.[lxxix] MyMedicare was formalised as an outcome of the Strengthening Medicare Taskforce.

In late December of 2023, the department released its Action Plan for the Digital Health Blueprint 2023–2033,[lxxx] which outlined its vision for the role digital health capabilities will play in delivering a more person-centred and sustainable health system by 2033.[lxxxi] The plan outlines how the department is taking a principles-led approach, that is person-centred, collaborative, trusted and enduring.

In realising the potential of digital interoperability, particularly in the health space, the United States and the EU at the forefront in achieving this. Australia would do well to learn from their experiences to realise the full benefits of health interoperability. While Australia has committed to data interoperability by establishing agencies and working parties, we have not yet moved into implementing it by establishing a national legal framework, rules and regulations, and explicit standards to govern its implementation. This work is essential, as without an agreed upon national framework with policy levers holding software providers accountable to certain standards, data interoperability in Australia will never reach its full potential in the health sphere. This is particularly important regarding adaptations that will be undoubtedly needed to healthcare data interfaces as the health system evolves. Having a published framework and policy in place will provide a guide for what is required if the software providers who own the data interfaces fail to comply to the changes needed as directed by the health providers. Establishing policy tools, which take the long-term view of data interoperability in the Australian healthcare sector, will save endless frustration and wasted efforts over time.

Challenges to digital interoperability

Digital interoperability in healthcare presents several significant challenges that must be addressed to realise its full potential. One of the primary challenges is the development and implementation of new funding models to ensure adequate resourcing for care delivered differently through electronic health records and interoperability. These funding models must be carefully designed to support the integration and maintenance of interoperable systems, which can be costly and complex.

The lack of standardisation across different healthcare systems further complicates interoperability efforts, leading to fragmented data and inconsistent patient care. Moreover, the increase in digital interoperability is expected to result in a higher demand for doctors, as they are required to provide significantly increased services while on call,

based on remote access to EHRs. This often occurs without a corresponding change in remuneration for on-call work. Many services previously funded by face-to-face care delivery models, such as prescription refills, monitoring, and interpreting remote patient data, are now expected to be performed without additional compensation or time allocation. This shift has led to increased burnout among doctors where the productivity demands associated with interoperability have risen without increased funding or time, exacerbating the strain on healthcare providers.

A major challenge that must be considered and continually revisited throughout the development of digital interoperability is ensuring that the overall healthcare system remains accessible to the entire community, including diverse patient groups such as the ageing population, individuals with lower literacy, and those without access to digital systems. It is essential to maintain a system that offers multiple access options, as the highest users of our healthcare system often have limited capacity to engage with digital health options. Their values and needs must be integrated into system changes to prevent significant disadvantages. While interoperability provides numerous benefits, changes that restrict face-to-face or other access methods can be counterproductive, particularly for those without carers to assist them. The COVID-19 pandemic highlighted the challenges of relying solely on digital solutions, as many high-risk patient groups struggled with low digital literacy and access. This underscores the importance of considering these factors when implementing digital interoperability and AI solutions in healthcare.

Although the benefits of digital interoperability are substantial and its progress is essential, these challenges must be carefully considered and addressed to ensure sustainable and effective healthcare delivery.

Connectedness

Connectedness plays a critical role in digital interoperability by enabling seamless interaction between different systems, technologies, and stakeholders.

Digital interoperability improves connectedness. In healthcare, digital interoperability and connectedness between patients and doctors are critical for improving care delivery, outcomes, and overall patient experience.

Real-time access to medical data through interoperable systems allows patients and doctors to stay connected between appointments, promoting a more collaborative approach to care. This enables improved communication between patients and health practitioners, allowing patients to communicate concerns, and doctors to provide timely advice or interventions using digital platforms, improving the continuity of care. This technology ensures treatment is based on a comprehensive understanding of the patient's medical history, resulting in more accurate diagnoses and effective treatments.

Furthermore, improved connectedness, allows the advancement of telemedicine, such as electronic prescribing and telehealth consultation, allowing patients to connect with doctors remotely, overcoming geographical barriers, and saving time. Moreover, automated reminders for medication, appointments, or health check-ups help patients stay on track, improving adherence to treatment plans, further empowering patients with their health. In sum, continuous monitoring, communication and connectedness between doctors and patients leads to early detection of potential health issues, allowing for timely interventions. This reduces hospital admissions and enhances overall care quality and better health outcomes.

Connected systems give patients greater control over their health data, allowing them to share information with multiple healthcare providers seamlessly. This creates a more holistic view of the patient's health, leading to better-informed decision-making by doctors. Additionally, with access to digital health records, through platforms such as the My Health Record, patients can engage more actively in their care, review treatment plans, and collaborate with their health practitioners to develop personalised care strategies.

Additionally, digital connected devices, such as wearables and remote health monitoring tools, allow patients to track vital signs, such as blood pressure, heart rate, and glucose levels. These devices automatically share data with healthcare providers, giving doctors real-time insights into a patient's condition and enabling proactive interventions. They also empower patients to manage chronic conditions more effectively through ongoing monitoring, reducing the need for frequent in-person visits to clinics. Similarly, in emergencies, connected systems can provide instant access to critical patient data, such as allergies, medications, and pre-existing conditions, enabling faster and safer

treatment decisions. This is particularly useful for first responders or emergency room staff who may not have time to collect a full medical history. By tapping into interoperable health data, they can make life-saving decisions with confidence.

Healthcare connectedness ensures healthcare providers can access the same medical records, pathology results, and patient's histories, regardless of the platform or hospital used. This reduces the risk of errors, such as incorrect prescriptions or redundant tests, and fosters collaboration among GPs, specialists, and patients. This digital connectedness supports integrated care models, where GPs, specialists, and other healthcare professionals work together, ensuring that patient care is collaborative and well-coordinated.

In sum, digital interoperability enables a connected, patient-centred healthcare system where doctors and patients can collaborate more effectively. It not only enhances communication and data sharing but also empowers patients to take control of their health. As technologies continue to evolve, interoperability will be increasingly important for creating a healthcare ecosystem that is efficient, personalised, and responsive to the needs of both patients and providers.

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