Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Standards

Best Practice Review of Health Information Modelling

March 2021

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.

- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.

- **Regulating health services —** Regulating medical exposure to ionising radiation.

- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.

- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.

- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

Overview of the health information function of HIQA

Healthcare is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is therefore imperative that information is managed in the most effective way possible in order to ensure a high-quality and safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests — if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst, not given.

In addition, health information has a key role to play in healthcare planning decisions — where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under section 8(1)(j), HIQA is charged with; evaluating the quality of the information available on health and social care and making recommendations in relation to improving the quality and filling in gaps where information is needed but is not currently available.

Information and communications technology (ICT) has a critical role to play in ensuring that information to drive quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to this, it can support a much faster, more reliable and safer referral system between the patient's general practitioner and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in Ireland's health and social care sector is highly fragmented with major gaps and silos of information which prevents the safe, effective, transfer of information. This results in the people who use the service being asked to provide the same information on multiple occasions.

In Ireland, information can be lost, documentation is poor, and there is over-reliance on memory. Equally, those responsible for planning our services experience great

difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, people are being encouraged to take more responsibility for their own health and wellbeing, yet it can be very difficult to find consistent, understandable and trustworthy information on which to base decisions on.

As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international best practice. A robust health information environment will allow all stakeholders: the general public, patients and service users, health professionals and policy makers to make choices or decisions based on the best available information. This is a fundamental requirement for a high-reliability healthcare system.

Through its health information function, HIQA is addressing these issues and working to ensure that high-quality health and social care information is available to support the delivery, planning and monitoring of services.

Under the Sláintecare Implementation Plan (2018)[(1)] which aims to implement the 10-year, cross-party vision for healthcare in Ireland, a key action is to 'identify improved information architecture, including standards, information and identity to underpin the delivery of integrated care'. In line with HIQA's recommendations development process, HIQA has undertaken an international best practice review on information modelling — the approach to modelling that countries have taken and the governance structures in place to support information modelling activities. The findings will inform the evidence base for a set of recommendations to the Minister for Health on the development on an information model for the collection, use and sharing of health information in Ireland.

Contents

Executive Summary

Accurate, relevant and timely information is essential in order to improve the provision of patient care, to inform better decision-making, monitor diseases, plan services, inform policy-making, conduct high-quality research, and to plan for future health and social care needs. This is recognised in the Sláintecare Implementation Strategy (2018)[1] which states that:

> 'Our system is highly fragmented and does not deliver care that is coordinated and integrated. The current system operates in silos. There is insufficient formal coordination across, and within, primary, community and social care and acute hospitals. The system has under-invested in the necessary professional staff, data and information, as well as ICT systems that are needed to routinely share information and better manage patients' care need'.

In Ireland, health information systems including national data collections and eHealth systems — have evolved over time in a largely uncoordinated fashion, resulting in isolated 'silos' of information with significant variation in quality, fragmentation, duplication, access problems, and increased costs. This is often because different computer systems do not 'talk to each other' because they send and understand information in different ways. In a well-designed health information system, a healthcare provider should be able to access quality patient information — including medication information, radiology reports and laboratory results, as well as clinical notes — in a timely way. At present, even in some quite advanced health information systems, administrative information, medication information, clinical notes, radiology reports and laboratory results are all captured on different computer systems and the information is not easily shared between them.[2] The ability of different computer systems to link or share information with each other is called interoperability.[3] Without interoperability, health information cannot be collected consistently, is open to misinterpretation, and it is difficult or impossible to share.

Every time patients interact with the healthcare system, whether visiting their general practitioner (GP) or attending a hospital visit, data is created. This data is potentially hugely valuable for managing patient care and for secondary use purposes. As mentioned, this data is often fragmented because datasets are often designed differently and in isolation for a specific purpose. Integrating information from a diverse domain such as healthcare, where there are very different datasets for different purposes, is challenging, as even within a single healthcare provider or speciality, there are often multiple ways of representing the same idea or concept. For example, there may be many different approaches to define clinical terms such as 'heart attack'. As a result, it can be difficult to define, interpret and exchange

information between different computer systems. This is because each computer system stores information in a different way.

Fortunately, there are solutions to improve how information can be structured to make it easier to share information. This can be done by designing health information system using common information models or by converting existing datasets so they follow the same common information model. Information modelling is an enabler to ensure that good quality information can be collected, used and shared across health services. To facilitate information modelling, a co-ordinated, national strategic approach to health information modelling is needed, supported by appropriate governance arrangements in place.

In the context of healthcare, an information model identifies the information that can be included when collecting and sharing clinical and administrative information. It allows key stakeholders, including clinicians, to identify the common categories of information that can be grouped together in a logical way (known as concepts) — such as patient, medications, diagnosis — that computer systems need to support. An information model not only captures the concepts, but also the relationships between each concept. These concepts are documented using an information model without being concerned about how it will be represented in technical implementations. It is a way to organise information so it can be collected (in a standard format) and re-used in a variety of different ways for different purposes. As mentioned, computer systems may use different descriptions and details for the same concept. An information model provides a layer of commonality to bridge the differences between computer systems to make it easier to collect, use and share information in a consistent way.

Clinical information models are a specific type of information model and are formal definitions for expressing the structure (syntax) and semantics (meaning) of the clinical content processed by health information systems, such as electronic health records. Clinical information models facilitate multiple tasks including data collection, exchange and query and analysis.[4]

International experience

Ireland has much to learn from the experience of other countries in the area of health information modelling. These lessons particularly relate to the governance arrangements that exist for health information and their experiences with stakeholder engagement.

All jurisdictions reviewed have strong leadership, governance and management in place with clear organisational responsibility for managing health information systems — including national data collections and eHealth systems. Each country has key organisations at national level with varying responsibilities in relation to

governing health information. For example, in Canada, two distinct organisations — Canada Health Infoway (Infoway) and the Canadian Institute for Health Information (CIHI) — are responsible for managing national eHealth initiatives and national data collections respectively. Formal governance arrangements for health information systems are in place in all five jurisdictions with good governance models established including national boards of eHealth, sub-committees and advisory committees where appropriate.

In several of the jurisdictions reviewed, including Australia, Canada, New Zealand and England, a single organisation is responsible for the development of health information standards including interoperability standards, such as Health Level Seven Fast Healthcare Interoperability Resources (FHIR), and clinical terminologies such as SNOMED CT. Countries such as New Zealand, Denmark and Canada also allocate responsibilities for eHealth at a regional or provincial level. In Ontario, four provincial committees have been established to meet the broader needs of governance in key areas of eHealth, with membership including subject matter experts from interest groups across the province. The IT Health Board is the governing body for health information standards in New Zealand. New Zealand also has the Health Information Standards Organisation (HISO), an expert advisory group for standards of the IT Health Board, working to advise on, identify, scope, develop and endorse health information standards and its work also focuses on information models.[1]In all jurisdictions reviewed, there is a long history in delivering national eHealth strategies. Denmark has had national eHealth strategies since the late 1990s. Since 1990, Canada has been working on the development of a national health information system infrastructure through a series of strategies and roadmaps. In 2017, the Australian Digital Health Agency delivered the Australian National Digital Health Strategy (2018-2022)[5,6] with interoperability, including health information modelling, and data quality highlighted as a key priority.

Most countries have 'information or interoperability frameworks' which detail the architecture, principles, vision and direction for the delivery of eHealth, an important artefact for information modelling. For example, the Australian Digital Health Agency developed an Interoperability Framework v2.0 which is a common reference point that provides guidance to business and information technology (IT) experts in delivering interoperable eHealth systems in Australia. Since 1990, Canada has been working on the development of a national health information system infrastructure through a series of roadmaps. It has developed a pan-Canadian blueprint that includes the 'conceptual information architecture' which is a high-level view of what information is found in an electronic health record. Information architecture was developed in New Zealand to enable interoperability to support a shared care approach to delivering healthcare to a patient. One of the key building blocks proposed was a common shared content model for structuring health information.

Denmark has a series of reference architectures that are used for specific use cases, including the collection of data.

In most countries, separate information models are used for the purpose of electronic health records and national data collections. The underlying data model used for modelling national data collections is the International Organisation for Standardisation (ISO) 11179 Metadata Registry (MDR) standard. In England, a National Health Service (NHS) Data Model and Dictionary exists and has evolved and been refined since 2005. There is a three-stage plan to move the Data Model and Dictionary to a single logical model with data collected for secondary uses, demonstrating its links to the data recorded in care records.

Australia has a long history of modelling health information. Historically, for modelling clinical information, Australia has used detailed clinical logical models to provide descriptions for clinical content used in different clinical scenarios. However, it is transitioning to the Health Level Seven FHIR standard to define its health information models. In all countries reviewed, there has been a significant shift in direction towards the Health Level Seven FHIR standard for implementing clinical information models.

Collaboration with key stakeholders plays a major role in the development of standards, including information modelling. Canada Health Infoway works with partners to accelerate the development and use of eHealth in Canada. Partners include federal, provincial and territorial governments and various industry stakeholders — such as technology vendors, provincial electronic health agencies, industry associations and healthcare organisations. In England, NHS Digital is working on several Health Level Seven Fast Healthcare Interoperability Resources (FHIR) projects, including collaboration with the Professional Record Standards Body (PRSB). Outlined in the recent interoperability roadmap, New Zealand plans to establish co-stewardship of data standards with medical colleges, national clinical networks and other stakeholders, following the approach of England's PRSB. In Canada, the four provincial committees on eHealth engage their constituents to ensure that decisions and direction are informed by the broader healthcare community. In Denmark, Medcom involves key stakeholders in the whole process of implementing a new standard or eHealth service, which they attribute to their successful adoption. In all jurisdictions reviewed there is good collaboration with vendors and all countries invest heavily in collaborating with and are well represented on industry and standards development organisations.

Irish landscape

In Ireland, since the publication of the eHealth Strategy for Ireland (2013), the strategic policy framework for eHealth in Ireland has evolved, with the Department of Health publishing the Sláintecare Implementation Plan in 2018. There is also work

underway on a national policy document on health information, the Health Information System Strategy. Under the Sláintecare implementation plan (2018), which sets out how to implement the 10-year cross-party vision for healthcare in Ireland, a key action is to 'identify improved information architecture, including standards, information and identity to underpin the delivery of integrated care'. (1)

Despite the acknowledged importance of health information for driving continuous improvement in health outcomes, and although there are number of strategies and plans in place, currently there are no common information models for the collection, use and sharing of health information in Ireland. However, there are numerous initiatives ongoing to support interoperability and information modelling. These include HIQA's multiple clinical datasets and a national standards catalogue published by the Health Service Executive Office of the Chief Information Officer to support the secure interoperable exchange of health information, including standards that apply to clinical information modelling. An information or architectural framework called the *Integrated services framework* has also been developed and an architectural principles document has been published to support the need for true interoperability. Other examples of ongoing projects include the national data dictionary (given that this review examines models that support the national data dictionaries for national data collections); the European Union Directive of Cross Border Exchange of Health Data which uses the Health Level Seven Clinical Document Architecture and underlying Health Level Seven reference information model to exchange clinical documents; and the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) which is a clinical terminology referenced in other countries as the coding used for binding to clinical information models.

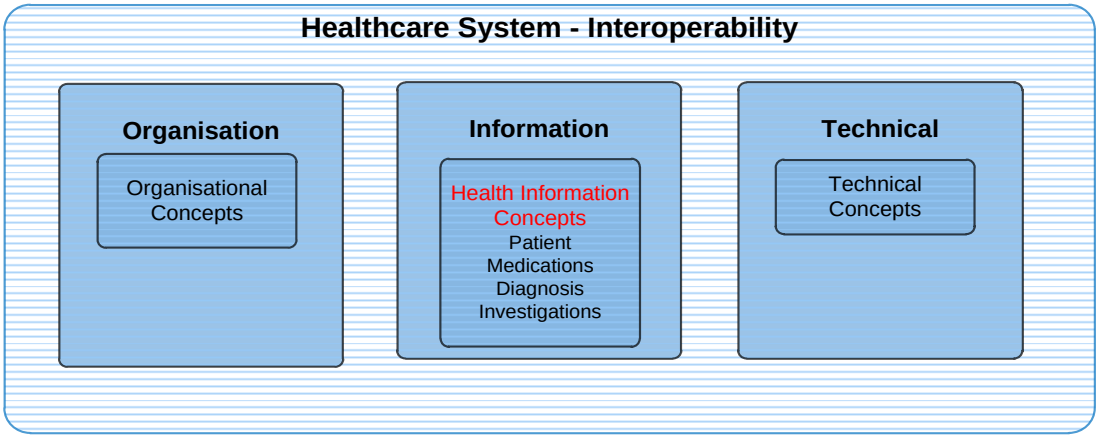
Having quality health information available when and where needed leads to quicker and more informed clinical decisions, and therefore improvements in efficiency, patient safety and patient outcomes. The use of information models ensures that information is described consistently, enabling the safe exchange of information which means that computers can share information that they can understand and interpret. Without implementing health information modelling, there is a risk that health information systems will continue to be designed in isolation and the opportunity to develop Ireland's health information system using a more national, strategic approach will be missed.

Chapter 1 Introduction

Often, different computer systems do not 'talk to each other' because they send and understand information in different ways. In a well-designed health information system, a healthcare provider should be able to access patient information including medication information, radiology reports and laboratory results, as well as clinical notes. At present, even in some quite advanced health information systems, administrative information, medication information, clinical notes, radiology reports and laboratory results are all captured on different computer systems and the information is not easily shared between them.(2)

The ability of different computer systems to link or share information with each other is called interoperability.(3) Without interoperability, health information cannot be collected consistently, is open to misinterpretation, and it is difficult or impossible to share. Interoperability should be viewed from three different perspectives — an organisational, information and technical perspective as outlined below. This project is concerned with all three perspectives.

Figure 1 Interoperability of health information from an organisational, information and technical perspective



- The organisational perspective is concerned with the understanding of the legislative, regulatory, healthcare and enterprise environment in which health information systems need to be deployed to enable improved healthcare delivery.
- The information perspective is concerned with how clinical, administrative or statistical information can be represented and interpreted. This requires agreement on a core set of health information concepts and relationships between concepts, as well as capturing relevant information patterns such as information governance and information quality.
- The technical perspective is concerned with the understanding of technical functionality for delivering health information systems.(7)

For example, in order to implement a national summary care record or a hospital-wide electronic health record, it is important to design, develop and deploy a system from all three perspectives, and not just a technology viewpoint. This is because healthcare is an example of a highly complex socio-technical system and is composed of many interdependent organisational, information and technical components as illustrated in Figure 1.

At the organisational level, a hospital is an organisation that has its own culture, politics, processes, policies and procedures. The organisation is also greatly influenced by its external environment such as legislation, government policies and regulation. Each hospital can have many departments covering different domains and specialities, both clinical and administrative. The people within the organisation and the departments they belong to develop their own culture and business processes to carry out their work.

At the information level, computer systems are designed with an understanding of the activities at an organisational level. However, even within a single organisation and speciality, there are often multiple ways of representing the same idea or concept. As a result, it can be difficult to share information between different computer systems as each computer system stores information in a different way. Concepts need to be standardised and described in a consistent way so information can be shared across organisations.

At the technical level, the standardised concepts are used to inform technical specifications for designing health information systems.

This review will focus on best practice on health information modelling, one of the key information areas that is needed for interoperability.

1.1 What is an information model?

An information model, in the context of healthcare, identifies the information that can be included when collecting and sharing clinical and administrative information. It allows key stakeholders, including clinicians, to identify the common categories of information that can be grouped together in a logical way (known as concepts) – such as patient, medications, diagnosis – that computer systems need to support. An information model not only captures the concepts, but also the relationships between each concept. These concepts are documented using an information model without being concerned about how it will be represented in technical implementations – it is a way to organise information so it can be collected (in a standard format) and re-used in a variety of different ways for different purposes.

Computer systems may use different descriptions and details for the same concept. An information model provides a layer of commonality to bridge the differences between computer systems to make it easier to collect, use and share information in a consistent way.

An information model outlines the structure the information should take. Structured data is highly organised and easily understood by computer systems. Examples of structured data include organising information by headings such as names, date and addresses, whereas unstructured data includes formats like free text, audio and video.[8]

For example, in healthcare, an information model that is agreed and describes all of the concepts required for prescription and dispensing information — that encompasses all stakeholder requirements — can then be re-used for different purposes across different clinical settings. By using the agreed, standardised information model it makes it easier to share information between healthcare providers, enabling activities such as electronic prescribing and dispensing and medication reconciliation on admission or following discharge to the community. See Appendix 1 for an example use case on an information model for community-based ePrescribing in Ireland.

The information model consists of a set of documented information structures, information processes, standards and guidelines used for implementing computer systems.

Clinical information models are a specific type of information model and are formal definitions for expressing the structure (syntax) and semantics (meaning) of the clinical content processed by health information systems, such as electronic health records. Clinical information models facilitate multiple tasks including data collection, exchange and query and analysis.[4]

1.2 Who does it benefit?

Having quality health information available when and where needed leads to quicker and more informed clinical decisions and hence improvements in efficiency, patient safety and patient outcomes. The use of information models ensures that information is described consistently, and enables the safe exchange of information which means that computers can share information that they can understand and interpret. As such, a wide range of stakeholders will benefit from interoperability supported by information models, including patients, healthcare providers and implementers. The benefits are outlined in more detail below:

- Patients benefit from interoperability in a number of ways. By ensuring that all relevant information relating to their care is available when and where it is

needed, the risk of an adverse event is reduced, quality of care is improved, and the unnecessary duplication of tests and investigations is eliminated. Specifically, patients will benefit from safer and timelier care.

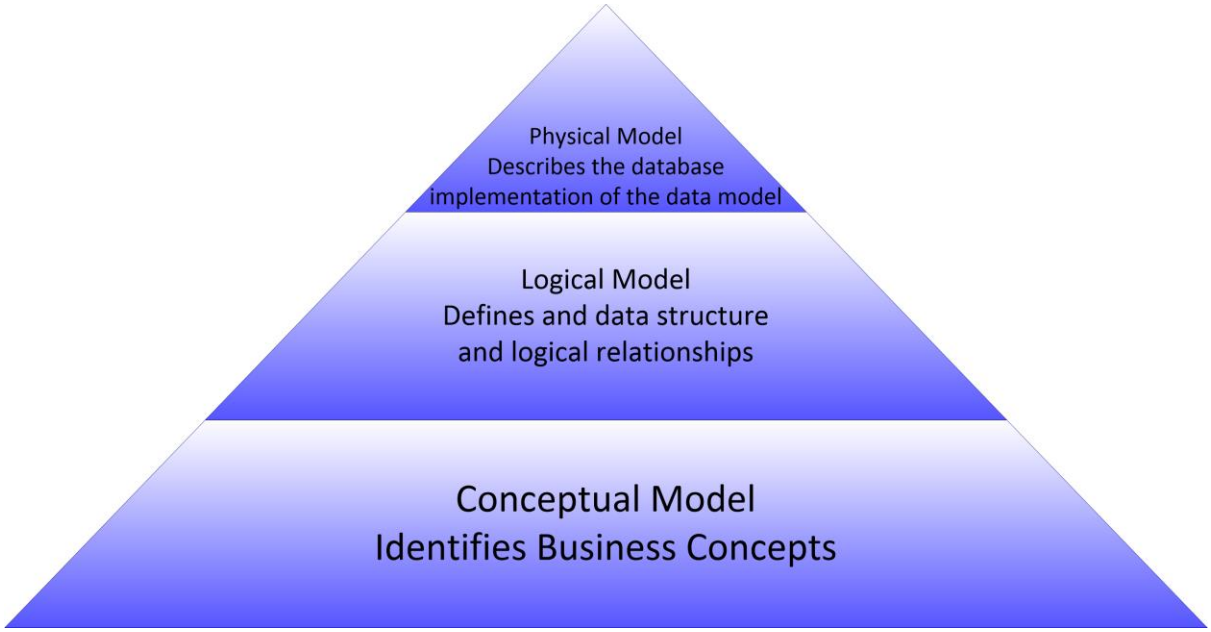
- Healthcare providers manage large volumes of health information to carry out a multitude of clinical tasks. Structured information enables better communication and transfer of knowledge between healthcare professionals. It is crucial for the continuity of care for patients and is essential for healthcare providers to be able to share documentation and communicate information readily to provide more efficient services.
- Implementers, when implementing computer systems, use information models to help reduce the time to design a computer system, improving the quality of the solution, and ensuring better integration with other computer systems.

1.3 Levels of information modelling

Integrating information from a diverse domain such as healthcare is challenging, as even within a single healthcare provider or speciality, there are often multiple ways of representing the same idea or concept. As a result, it can be difficult to define, interpret and exchange information between different computer systems. This is because each computer system stores information in a different way.

There are different levels of information models that help computer systems to understand and interpret information, namely conceptual, logical and physical models that have ascending levels of details. Figure 2 illustrates the different levels of information models and a description of each level is described below.

Figure 2 Levels of information modelling



- Conceptual modelling represents real world problems or the concepts that exist at a high level to describe a high-level business view. The conceptual model describes the real world in very general terms. This is very effective for communicating with the business to understand and define the business processes within an enterprise such as healthcare. The conceptual data model represents the overall structure of data required to support the business requirements independent of any software or data storage structure.

  For example, a conceptual model captures the organisational structures of a hospital, the size of the hospital, the clinical specialities and whether the organisation is a network or a single entity, that is to say, does it belong to a hospital group. Examples of key business processes that occur in a hospital are electronic referrals, electronic prescribing, disease-specific care pathways, and hospital discharge. Processes or single events that occur in a hospital-wide enterprise can include performing a surgical procedure or the generation of a prescription. Business processes aimed at improving the care of an organisation's population of patients can include the creation and use of registries of patients with chronic illnesses.

- The logical information model includes textual descriptions of the information and defines the relationships between the various concepts. It is described in business language that should be easily understood and verified by business users and domain experts. The logical model helps stakeholders to understand the details of the information, but not how it is implemented. It builds upon the information requirements provided by the business group. It includes a further level of detail, supporting the information requirements. Like the conceptual data model, the logical data model is independent of specific database and data storage structures.

  For example, the logical information model is created for a business process, such as electronic prescribing, and captures the information that is needed for healthcare professionals to conduct their work and tasks associated with electronic prescribing. If two systems want to communicate and they use the same logical model it makes it easier to share information in a safe and effective way.

  The physical data model allows computer engineers to use the logical model to form the basis for designing databases including the tables (entities), data elements, data types and their relationships. It can be understood by both software engineers and domain experts who have expertise in physical data modelling.

1.4 Interoperability

Information modelling is an enabler towards interoperability. Without interoperability health information cannot be collected consistently, is open to misinterpretation, and it is difficult or impossible to share.

Various organisations and individuals have attempted to identify and define the different types of interoperability in the healthcare domain. The Healthcare Information and Management Systems Society (HIMSS) *Dictionary of Healthcare Information Technology Terms, Acronyms and Organisations* identifies 17 different definitions of interoperability ranging from technical, organisational, functional, political, legal and social interoperability.(9) However, the three major types of interoperability relevant for this best practice review are technical, semantic and process interoperability outlined below:

- Technical interoperability is the exchange of data between computer system A and computer system B. Computer systems do not know about the meaning of the data that is being exchanged.
- Semantic interoperability guarantees that system A and system B understand the meaning of the data in the same way. It is the ability of systems to use and interpret the data that is exchanged in a meaningful way. For example, SNOMED CT[1] codes are bound at this level facilitating the exchange of meaningful information.
- At the organisational or process level, interoperability is required across common business processes and workflow, to enable seamless provision of healthcare across healthcare providers when exchanging data.

A prerequisite for semantic interoperability is agreement of the data content and the information models. An overview of the relevant international interoperability standards that are used to implement clinical information models are described in Chapter 2 of this best practice review.

1.5 Purpose of the best practice review

The purpose of this best practice review is to document national and international evidence and best practice in relation to information models for the collection, use and sharing of health information. This review examines how eHealth, including electronic health records and national data collections, are modelled internationally. A summary of international experience is described in section 1.7 below.

This best practice review focuses on the different approaches to information modelling that countries have taken and the governance structure in place to

[1] Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) – the primary clinical terminology.

support information modelling activities. The findings will inform the evidence base for a set of recommendations to the Minister for Health on the development on an information model for the collection, use and sharing of health information in Ireland. The term 'health information systems' will be used throughout this report to encompass both electronic health record systems and national data collections.

This review was undertaken as per HIQA's legislative remit under the Health Act 2007 and subsequent amendments to the Act.[10] Under the Health Act 2007, HIQA has a statutory remit to develop standards, evaluate information and make recommendations about deficiencies in health information. The responsibilities of HIQA in this regard are outlined in the Act as follows:

- Section 8(1)(i): to evaluate available information respecting the service and the health and welfare of the population
- Section 8(1)(j): to provide advice and make recommendations to the Minister for Health and the HSE about deficiencies identified by HIQA in respect of the information referred to in paragraph (i).

Under the Sláintecare implementation plan (2018),[1] which sets out how to implement the 10-year, cross-party vision for healthcare in Ireland, a key action is to 'identify improved information architecture, including standards, information and identity to underpin the delivery of integrated care'. Sláintecare recognises the importance of quality health data and information to drive improvements in the future of healthcare in Ireland citing 'electronic health is a critical enabler to implement the change required to deliver an integrated, universal, high quality health system'. It is, therefore, essential that information is managed in the most effective way possible in order to ensure a high-quality safe service.

1.6 Methodology

The focus of this best practice review is to determine current practices internationally in relation to information modelling for the collection, use and sharing of health information. The review will focus on the different types of models — conceptual models, logical and physical models — used for specific use cases and the governance structures in place to manage and maintain models.

In line with HIQA's recommendations development process, a detailed desktop review was undertaken to identify examples of best practice internationally. An initial desktop scoping review indicated variations internationally on how countries model health information and highlighted how national electronic health programmes were at various stages of development. There were few examples of published literature and public-facing articles in the area. Academic evaluations were also limited but included, where available and relevant.

A range of countries was selected including Australia, Canada, New Zealand, England and Denmark. Australia and Canada have deep experience and interest in health information modelling and have published blueprints and information models for their electronic health records and data models for their national data dictionaries to support national data collections and national datasets. Virtual interviews were held with countries to ensure the most up-to-date information was gathered and core themes were discussed based on key questions that were prepared to guide the discussion. During these calls, information modelling was explored under the following themes:

- Type of information modelling approaches used to model health information
- Use of international standards for clinical information modelling and reason for choosing this option
- Governance structures in place to maintain controls over the creation, ongoing development and use of information models.

Finally, the review was analysed and key findings and themes emerged to inform the best practice review. An overview of information modelling in each country is provided in Chapters 3 to 7 of this report.

1.7 Summary of international evidence

This section highlights the key findings from examining best practice on information modelling internationally. Chapter 2 describes the standards that are cited in this section in detail. The following themes were identified based on the international evidence collated: leadership, governance and management, maturity of ehealth services, information frameworks, interoperability, information modelling, governance of eHealth, stakeholder engagement and collaboration with national and international standards development organisations. All themes are important considerations for modelling health information. In most of the countries reviewed, separate models were used for eHealth developments and national data collections.

1.7.1 Leadership, governance and management

All countries reviewed have strong leadership and clear organisational responsibility for governing health information at a national level. Each country has key organisations at state level with varying responsibilities in relation to the collection, use and sharing of health information. For example, in Canada, two distinct organisations — Canada Health Infoway (Infoway) and the Canadian Institute for Health Information (CIHI) — are responsible for managing national eHealth initiatives and national data collections respectively. In Denmark, at the governmental level, the Ministry of Health consists of a department as well as a number of boards and authorities that work to ensure a well-functioning and efficient health system. Countries such as New Zealand, Denmark, Canada and

England also allocate responsibilities for eHealth at a regional or provinicial level. In New Zealand, given that the district health boards are autonomous, there is a strong tendency for local eHealth services to take precedence over national projects.

All countries demonstrated significant investment to move the eHealth agenda forward. In Australia, the federal government invested heavily to progress Australia's eHealth landscape with a radical shift in digital health policies over the last decade and the establishment of a new agency, the Australian Digital Health Agency. All countries reviewed also developed national eHealth strategies. Denmark has had national eHealth strategies since the late 1990s.

1.7.2 Maturity of eHealth services

A common theme identified in all countries is the high level of maturity of eHealth services and the maturity of national data collections. The eHealth developments examined included the use of health identifiers, electronic health records, electronic prescribing, and electronic referrals. All countries have operationalised individual health identifiers — considered a foundational enabler for linking systems and sharing information — electronic prescribing and electronic referrals to varying degrees. Most countries are advanced in terms of their electronic health record programmes but at different stages of development. New Zealand has implemented a regional shared care record, while England has implemented summary care records and local health and care record exemplars, and electronic referrals are linked to the national electronic health record or 'My Health Record' in Australia. In Denmark, all general practitioners (GPs) maintain electronic health records, and information from these electronic health records is added to national health registries and all prescriptions and referrals are digital.

All countries have information systems for the collection, reporting and analysis of health data (national data collections). For example, New Zealand has a centralised structure in place for health and social care data collections, with the Ministry's obligation to collect data stipulated in different pieces of legislation. There is a secure network between the Ministry of Health and the district health boards for the transfer of data and all national collections data is stored in the Ministry's data warehouse.

In England, National Health Service (NHS) England has power under the Health and Social Care Act 2012 to direct NHS Digital to collect information from health organisations. The general purpose for doing this is to establish collections of information that can be used to monitor how well the NHS is performing and the quality of care provided. As the data is held centrally, it can be linked to provide information that would not otherwise be possible. Denmark has developed very rich datasets over many decades.

1.7.3 Information frameworks

Most countries have 'information or interoperability frameworks' which detail the architecture, principles, vision and direction for the delivery of eHealth, an important artefact for information modelling. For example, the Australian Digital Health Agency developed an *Interoperability Framework v2.0* which is a common reference point that provides guidance to business and information technology (IT) experts in delivering interoperable eHealth systems in Australia. Since 1990, Canada has been working on the development of a national health information system infrastructure through a series of roadmaps. It has developed a pan-Canadian blueprint that includes the 'conceptual information architecture' which is a high-level view of what information is found in an electronic health record. Information architecture was developed in New Zealand to enable interoperability to support a shared care approach to delivering healthcare to a patient. One of the key building blocks proposed was a common shared content model for structuring health information. Denmark has a series of reference architectures that are used for specific use cases including the collection of data.

1.7.4 Interoperability

Technical interoperability or data exchange is well advanced in all countries. In Canada, clinical, administrative, drug, and diagnostic data are exchanged provincially, territorially and federally. In New Zealand, exchange of data for clinical referrals, orders, discharges, prescribing and dispensing, and results management are in place. Health data in England are being exchanged for numerous purposes across all care settings including social care. The uses of these data are for both individual care and secondary uses.

Different standards are used for different use cases. For example, in New Zealand, regional clinical data repositories for electronic referral, electronic order, transfer of care and shared care solutions have been built to different standards around the country and cannot interoperate in some cases. Common interoperability standards used across Australia, Canada, New Zealand, England and Denmark include Health Level Seven v2.x, Health Level Seven Clinical Document Architecture standard, the Health Level Seven Fast Healthcare Interoperability Resources (FHIR) standard and Integrating the Health Enterprise (IHE) profiles. The ISO/IEC 11179 standard, information technology for metadata registries, is used in most jurisdictions to underpin the data model for national data dictionaries used for national data collections.

In England, Canada and Denmark, there is support for Health Level Seven version 3. Canada was heavily involved in the development of Health Level Seven version 3 and Denmark endorse the Health Level Seven version Reference Information Model (RIM) in the development of messaging. In England, Health Level Seven version 3 is

used for national components such as general practice and personal demographic service, using a bespoke extensible mark-up language (XML) standard for several secondary uses collections. Other key standards and eHealth interoperability initiatives of importance used in all countries include: Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) – the primary clinical terminology, Digital Imaging and Communications in Medicine (DICOM) – international imaging standard and Integrating the Health Enterprise.

There has been a significant shift in direction towards the Health Level Seven Fast Healthcare Interoperability Resources (FHIR) standard. Australia, New Zealand and England have recommended it for future standards development and the development of newer specifications for eHealth.

1.7.5 Information modelling

In 2003, the Australia Institute of Health and Welfare published a report on a national health information model (version 2) which described an enterprise-wide — that is to say, covering all of healthcare — conceptual model. In the same year, Denmark attempted a similar smaller scale project, having developed a hospital-wide enterprise model for the collection, use and sharing of health information. Neither model is operational but part of the national health information model (version 2) was re-used for modelling health information for national data collections in Australia. In Canada, high-level conceptual models are used in the pan-Canadian Blueprint for the electronic health record, and the Canadian Institute for Health Information (CIHI) Reference Data Model (CRDM) standard is a standardised, high-level, corporate-wide reference data model underpinning its national data dictionary.

In most countries, separate models are used for the purpose of electronic health records and national data collections. The underlying data model used for modelling national data collections is the International Organisation for Standardisation (ISO) 11179 Metadata Registry (MDR) standard. In England, an NHS Data Model and Dictionary exists that has evolved and been refined since 2005. There is a three-stage plan to move the Data Model and Dictionary to a single logical model with data collected for secondary uses, demonstrating their links to the data recorded in care records.

Different types of standards are used for structuring health information for the collection, use and sharing of health information among electronic health records and other eHealth services. For example, detailed clinical models have historically been used in Australia and New Zealand to provide descriptions for structuring clinical information for the My Health Record, used in different clinical scenarios. OpenEHR archetypes were then used to enable implementation of the clinical logical models, with the Health Level Seven Clinical Document Architecture (template level) used for their document exchange or exchange of clinical documents. In Denmark,

national models are being used though based on international standards for modelling. The Danish Agency for Digitization has developed shared model rules aimed at promoting modelling that can ensure that the data collected and handled in public organisations, including healthcare services, can be easily understood and recycled across the public sector. A priority for New Zealand is to focus on the patient summary and they intend to follow the information model that the Joint Initiative Council use for its patient summary.

Historically, for modelling clinical information, Australia has used detailed clinical logical models to provide descriptions for clinical content used in different clinical scenarios. The Digital Health Australia Agency uses the openEHR archetypes as the conceptual basis for its clinical logical models and the Health Level Seven Clinical Document Architecture (template level) for its document exchange or exchange of clinical documents.

Australia has developed a single framework within which different information models are adopted for different purposes and scopes of use. Australia has a long and strong history of modelling health information.

1.7.6 Governance of eHealth

In all the countries reviewed, there is strong governance structures in place to enable successful interoperability of health information systems, with clearly defined organisations responsible for the governance of developing standards for interoperability which covers information modelling.

In Canada, four provincial committees have been established to meet the broader needs of governance in key areas of eHealth, with membership including subject matter experts from interest groups across the province. The IT Health Board is the governing body for health information standards in New Zealand. The Health Information Standards Organisation (HISO) is the expert advisory group for standards of the IT Health Board, working to advise on, identify, scope, develop and endorse standards and information models. New Zealand also plans to regularly assess functionality, standards, adoption level and governance.

In Denmark, a national board has been set up to advise the minister of responsibility for overall IT architecture and setting standards. An advisory committee has been established to assess and select standards and assess architecture in the field of health to satisfy the Health Data Authority's recommendations prior to a possible presentation to the National Board of eHealth.

1.7.7 Formal agreements for national data dictionaries

The National Health Data Dictionary is an initiative under the Australian National Health Information Agreement, where all parties agree that the collection,

compilation and interpretation of national information are appropriate and carried out efficiently. Data dictionaries describe the information available within national data collections and promote consistency across the collections, supporting the use of nationally agreed protocols and standards. This requires agreement on definitions, standards and rules for collecting information, and on guidelines for coordinating the access, interpretation and publication of national community services and health information. Governance of national data collections in New Zealand is guaranteed by the Ministry of Health which signs an operational policy framework (OPF) with the 20 district health boards each year. The OPF sets out the business rules, policy and guideline principles that outline the operating functions of district health boards and the responsibilities of the Ministry of Health in relation to national health information management and reporting requirements.

1.7.8 Stakeholder engagement

Stakeholder engagement plays a key role in the development of standards, including information modelling. Canada Health Infoway works with partners to accelerate the development and use of eHealth in Canada. Partners include federal, provincial and territorial governments and various industry stakeholders — technology vendors, provincial electronic health agencies, industry associations and healthcare organisations. In England, NHS Digital is working on several Health Level Seven fast healthcare interoperability resources (FHIR) projects, including collaboration with the Professional Record Standards Body (PRSB). Outlined in the recent interoperability roadmap, New Zealand plans to establish co-stewardship of data standards with medical colleges, national clinical networks and other stakeholders, following the approach of England's Professional Records Standards Body. In Canada, the four provincial committees on eHealth engage their constituents to ensure that decisions and direction are informed by the broader healthcare community. In Denmark, Medcom involves key stakeholders in the whole process of implementing a new standard or eHealth service, which they attribute to their successful adoption.

1.7.9 Engagement with vendors

In Australia, generally vendors can play a role in working groups (including Health Level Seven International, Health Level Seven Australia and Standards Australia) with varying powers. Canada Health Infoway works with partners including technology vendors to accelerate the development and use of eHealth in Canada. Denmark hosts meetings where software developers, including vendors, meet to test each other's systems and request and read data. In England, NHS Digital is working on several Health Level Seven fast healthcare interoperability resources (FHIR) projects, including collaboration with the INTEROpen vendor group to provide clinical validation of FHIR profiles for use in the national health and social care services.

1.7.10 Collaboration with industry and standards development organisations

Australia and Canada invest heavily in collaborating with and are well represented on industry and standards development organisations. As part of the transition to Health Level Seven Fast Healthcare Interoperability Resources (FHIR), the Digital Health Australia Agency has introduced a process to develop FHIR profiles in a collaborative, open and transparent process in partnership with standards organisations and industry, such as Standards Australia and Health Level Seven Australia. In Canada, there is a dedicated team to liaise with international health-related standards development organisations such as Health Level Seven, and they were involved heavily with the development of Health Level Seven version 3.

Chapter 2 will describe the standards that are cited in this section in detail. Chapters 3 to 7 detail the countries reviewed internationally followed by the current landscape in Ireland. The best practice elicited from this review will inform HIQA's recommendations on an approach to information modelling for the collection, use and sharing of health information in Ireland.

Chapter 2 International interoperability standards

This chapter summaries international standards development organisations andthe standards they have developed and published relevant to this review, specifically the standards that support the implementation of clinical information models. The technical standards that exist for the purpose of defining and implementing clinical information models and for defining national data collections are included in this chapter.

- Based on the countries reviewed, key standards emerged and are used for the following purposes: Clinical information models: to define clinical information models, the International Organisation for Standardisation ISO3972: Standard for Detailed clinical models is used.Clinical information models: to implement clinical information models, the Health Level Seven (HL7) Clinical Document Architecture, Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) and openEHR archetypes were used.
- National data collections: to underpin the national data dictionaries and data models for national data collections, the International Organisation for Standardisation 11179: Standard for metadata registry was used.

The number of healthcare information and communication technology (ICT) standards available is summarised in a report prepared by Empirica GmbH,[2] who conducted a report on behalf of the European Commission, identifying 22 different ICT standards in healthcare.(11) As outlined by Empirica GmbH, the major standards development organisations that play a leading role in electronic health record (EHR) standards development and clinical information modelling include:

- International Organisation for Standardisation (ISO): the largest developer of world-wide standards including healthcare standards.
- European Committee for Standardisation (CEN): the principal standards development organisation in Europe.
- Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) International: the developer of the SNOMED CT clinical terminology standard.
- Health Level Seven (HL7): the developer of the most widely used standards for electronic messages and documents in healthcare.
- OpenEHR: an open source community for electronic health records.
- Integrating the Healthcare Enterprise (IHE): a major eHealth systems interoperability initiative.

[2] An independent economic and social science consultancy firm.

2.1 Interoperability standards

The most relevant standards on information modelling have been identified in Table 1 and outlined in detail in section 2.2 below.

Table 1 – Standards development organisations in healthcare and standards for information modelling

Standards development organisation	Role	Standards for information modelling
International Organisation for Standardisation (ISO)	An independent, non-governmental organisation who develop International Standards, one area being in healthcare. International Organisation for Standardisation (ISO) standards make it easier to compare health services, exchange information, aggregate data and safeguard the privacy of an individual's health.	ISO/IEC 11179 for metadata registry ISO 13972 for Detailed clinical models ISO/CEN 13606 standard electronic health record communications
OpenEHR	A not-for-profit organisation, whose mission is to enable the use of ICT to effectively support healthcare and medical research through the creation of open specifications, open source software and tools.	OpenEHR archetypes and CEN 13606
Health Level Seven (HL7)	Health level seven, the organisation, is a U.S. based non-profit ANSI accredited Standards Development Organisation. Health level seven develops standards to support the exchange,	Health Level Seven (HL7) Clinical Document Architecture Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) Health Level Seven (HL7) version 3 Health Level Seven (HL7) version 2[3]

[3] HL7 version 2 is concerned with health data exchange and does not play a role in information modelling and is described in this document because it is cited regularly throughout this document.

	management and integration of healthcare information and provide a suite of interoperability standards including Health Level Seven version 2.0, version 3.0, clinical document architecture and Health Level Seven Fast Healthcare Interoperability Resources (FHIR).	

2.2 International Organisation for Standardisation (ISO)

The International Organisation for Standardisation (ISO) is an independent, non-governmental membership organisation and the largest developer of world-wide voluntary international standards, including in healthcare. International Organisation for Standardisation (ISO) is made up of 165 member countries. Experts develop the standards through a consensus process reflecting international experience and knowledge.

The following ISO standards will be described throughout section 2.2.1-2.2.3:

- *International Organisation for Standardisation 11179: Standard for metadata registry*[12]
- *International Organisation for Standardisation ISO3972: Standard for Detailed clinical models*[13]
- *International Organisation for Standardisation (ISO)/European Committee for Standardisation (CEN):13606 Standard for electronic health record communications.*[14]

2.2.1 International Organisation for Standardisation (ISO) 11179 Metadata Registry (MDR) standard

The International Organisation for Standardisation 11179: Standard for metadata registry standard is used for representing metadata for an organisation in a metadata registry. Metadata is data that describes other data. Meta is a prefix that in most information technology uses means 'an underlying definition or description'. A metadata registry is a central location in an organisation where metadata definitions are stored and maintained.

Metadata summarises basic information about data, which can make finding and working with particular instances of data easier and makes data more understandable and shareable. For example, the data elements 'author, date

created, date modified and file size' are examples of very basic document metadata. Having the ability to filter through metadata makes it much easier to locate a specific record. In addition to document files, metadata is used for various other data formats including: images, videos, spreadsheets and web pages.[15]

2.2.2 International Organisation for Standardisation (ISO) 13972: Detailed clinical models

Detailed clinical models are basic information blocks that provide a way to structure medical information. These building blocks are independent of the context in which they are used or the technical implementation. Detailed clinical models are descriptions of clinical information that include the clinical knowledge on the concept, the data specification, a model and, where possible, technical implementation specifications.

Detailed clinical models are formally described as 'small items of clinical, preventive and care information that are well defined and for which knowledge, data definition, vocabulary binding, and information models for use in information and communication technology are standardised and reusable over domains, purposes, standards and implementations.'[16]

The International Organisation for Standardisation ISO13972: Standard for Detailed Clinical Models standard[13] was published in 2015 and provides guidance on how a detailed clinical model should be represented and any quality criteria that needs to be met. The standard does not focus on the creation of detailed clinical models as it provides information about methods and requirements to collect, analyse and specify the clinical contents and structure of detailed clinical models. The categories included in the *International Organisation for Standardisation ISO13972: Standard for Detailed Clinical Models* include: 1) clinician involvement, 2) content specification 3) modelling approach 4) governance and repository and 5) patient safety measures.

The aim of designing detailed clinical models is to support the consistent use of medical data among different healthcare organisations and applications by ensuring that they all use the same common requirements. This will make it easier for organisations to support multiple technical standards to exchange the same information. Implementing detailed clinical models have various benefits, such as:

- supporting stakeholders (clinicians and health informaticians) to understand the complex healthcare business in order to understand the clinical content necessary to design, create and maintain healthcare information systems.
- integrating different standards with each other, in particular medical knowledge, clinical terminology, workflow, and information modelling. Clinical terminologies are structured vocabularies covering complex concepts such as diseases, operations, treatments and medicines.

- facilitating the secondary use of clinical data for research and epidemiological studies.

Overall, detailed clinical models specify clinical content for use in electronic health records, messages — which refers to a unit of information that is sent from one system to another — and documents, user interfaces and medical devices. They also specify clinical content for use in national registries. The overall aim is that the specifications for a specific concept, such as diagnosis, are consistent for all these functions.

The International Organisation for Standardisation ISO13972: Detailed Clinical Models standard determines detailed clinical model governance rules to provide integrity of concepts of all detailed clinical model attributes. Moreover, to ensure developing quality detailed clinical models, the standard expresses development and the methodology rules associated with detailed clinical models. It also outlines principles for use to support the production of quality detailed clinical models to minimise risk and ensure patient safety.[17]

2.2.3 International Organisation for Standardisation (ISO)/European Committee for Standardisation (CEN) 13606

This standard was originally developed by the European Committee for Standardisation (CEN) which is the principal standards development organisation in Europe. The European Committee for Standardisation (CEN) brings together the national standardisation bodies of 33 European countries. CEN provides a platform for the development of European standards and other technical documents and supports standardisation activities in relation to a wide range of sectors including healthcare. The standards development process is based on consensus and channelled through the national standardisation organisations.

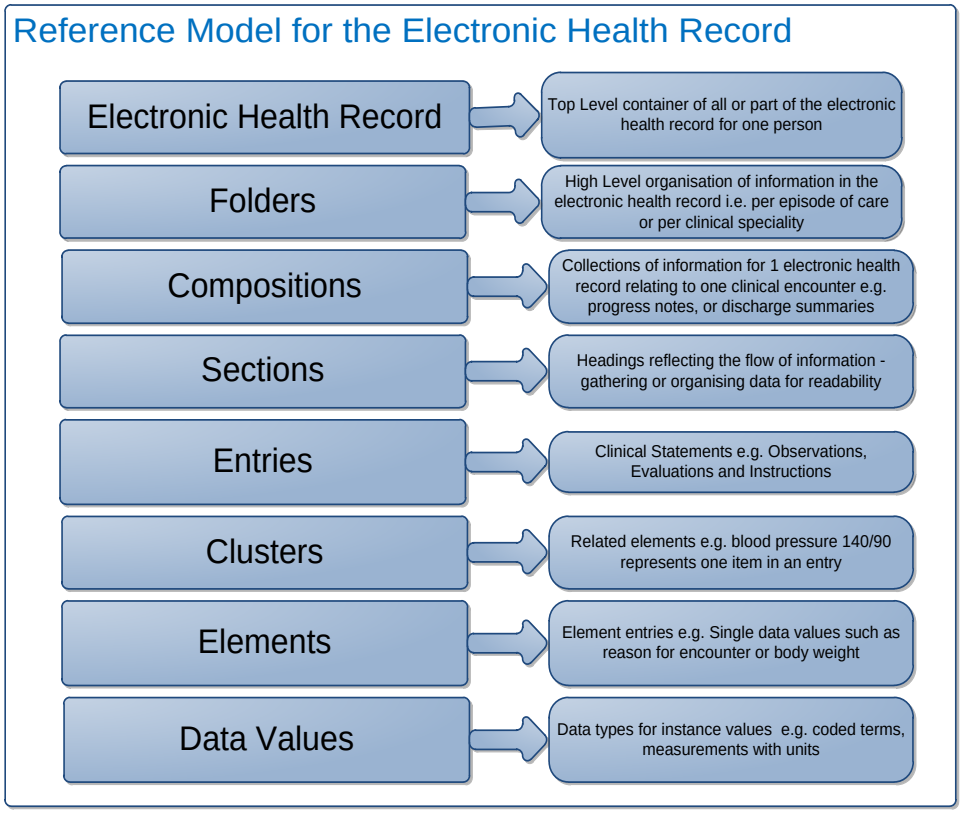
The *International Organisation for Standardisation (ISO)/European Committee for Standardisation (CEN) 13606 Health Informatics – electronic health record Communication*[14] is the first formal standard for electronic health record communications and was officially approved by the ISO in February 2008.

The standard consists of five parts and describes how information can be structured using a reference model to enhance communicating different parts or all of the electronic health record of a single subject of care (patient) between different systems or a centralised electronic health record data repository. It does not provide a specification for storing information as it does not define the database design.

Part one of the standard defines a useful hierarchy of clinical information and illustrates how information should be organized to enable interoperability (see Figure 3 below). In summary, the components of the reference model are made up of an

extract which is the container that holds all of the components. Compositions correspond to clinical documents such as a referral, clinical summary or discharge summary and are grouped into folders. Folders may signify information about the patients visit. A section refers to clinical headings, with clinical information organized under these headings. The headings do not store information. Entries or simple clinical statements are stored within the compositions. Entries are composed of types of clusters of related elements, single value elements and data values which are illustrated in Figure 3.

Figure 3: Reference Model ISO/CEN 13606



2.3 openEHR

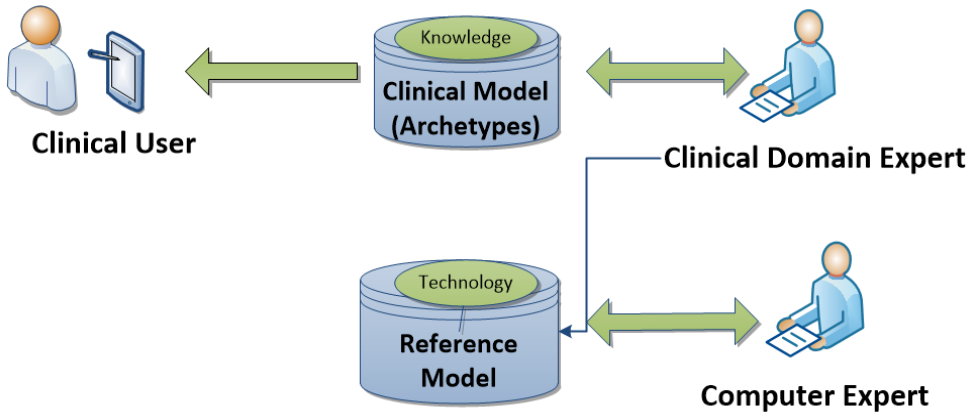
OpenEHR International[18]l is a non-profit organisation originally established in 2003. Its mission is to enable the use of ICT to effectively support healthcare and medical research and it aims to achieve this through the creation of open specifications, open source software and tools.[19] The success of openEHR is most notably due to the formal acceptance of CEN 13606 as a European and ISO standard as described in 2.2.3 above. This is based on many aspects of the openEHR design approach, and part 2 of the *International Organisation for Standardisation (ISO)/European Committee for Standardisation (CEN):13606 Standard for electronic health record communications*[14] standard is a snapshot of the openEHR archetype specifications described in 2.3.2 below. The openEHR Foundation works closely with other

standards organisations on electronic health record-related and clinical modelling standards.

2.3.1 OpenEHR Methodology – dual model approach

The openEHR methodology is based on a dual model approach (Figure 4) that includes two separate models — an archetype model and a reference model. The reference model is based on the European Committee for Standardisation (CEN):13606 reference model defined in 2.2.3 above. The archetype model or knowledge level formally models clinical content such as blood pressures or laboratory results in the form of 'archetypes'. This is further explained in section 2.3.2.

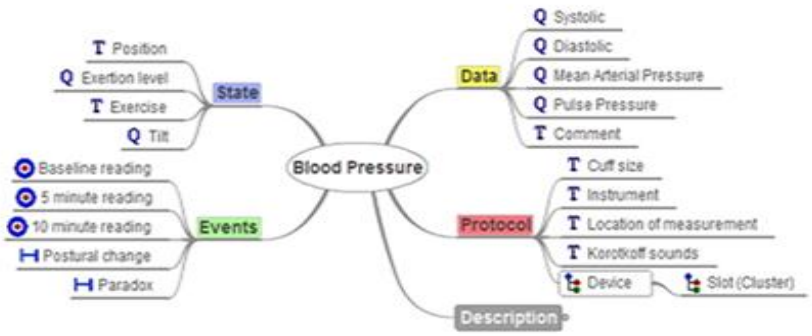
Figure 4 – Dual Model Approach



2.3.2 OpenEHR archetypes

An openEHR archetype is the model that is used for describing clinical concepts. Archetypes are used to collect, store, retrieve, represent, communicate and analyse clinical data. Archetypes represent a single clinical concept and define the content and structure of the data. Archetypes are used to collect, store, retrieve, represent, communicate and analyse clinical data. This ensures that only data of a certain quality can be included in the electronic health record. An archetype is hierarchical in structure and includes a maximal set of data. Archetypes are designed by constraining (adding certain rules) to the information building blocks (or data structures) in the reference model. As archetypes define clinical concepts in a standardised way, for example a blood pressure definition (see figure 5), information can be shared and used across different health information systems.[20]

Figure 5 – A blood pressure 'archetype' illustrated using a mind map



There are five attributes to fully describe an archetype and to ensure the most accurate interpretation of a blood pressure reading:

- Data: Required data associated with a blood pressure
- State: the position of the person at the time of the measurement (standing/sitting)
- Protocol: size of cuff used for blood pressure measurement
- Event: estimation of the average blood pressure over a 24-hour period
- Description: any further description needed.

An archetype is designed so it is reusable across different healthcare systems and is clinically meaningful. Archetypes are the result of consensus between healthcare providers to ensure the inclusion of all relevant data is documented about a health topic (for example, blood pressure, diagnosis, lab test and so on). It is intended that people with medical knowledge, who understand what makes clinical content valid, should author them. Combinations of archetypes can make up open electronic health record templates and can be used as screen forms and printed documents. Data entry takes place at the template level. OpenEHR archetypes were adopted by ISO and are defined in the ISO 13606 Part 2: Archetype interchange specification.[21]

2.4 Health Level Seven (HL7) International

Founded in 1987, Health Level Seven (HL7) International is a not-for-profit, American National Standards Institute (ANSI)-accredited standards developing organisation. It is dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.[22]

Health Level Seven provides standards for interoperability that improve care delivery, optimise workflow, reduce ambiguity and enhance knowledge transfer

among all of its stakeholders, including healthcare providers, government agencies, the vendor community, fellow standards development organisations and patients.

Messaging standards outline the structure, content and data requirements of electronic messages to enable the effective and accurate sharing of information. The term 'message' refers to a unit of information that is sent from one system to another, such as between a laboratory information system and a general practitioner's clinical information system. The main HL7 messaging and document exchange used in healthcare are:

- Health Level Seven version 2.x standards
- Health Level Seven version 3 standard
- Health Level Seven Clinical Document Architecture standard
- Health Level Seven Fast Healthcare Interoperability Resources (FHIR) standard.

2.4.1 Health Level Seven version 2.x

The Health Level Seven version 2.x standard provides specifications for messages to support the sharing of information on admission to and transfer within and between healthcare facilities. It provides messages to support many scenarios, including the ordering of laboratory investigations, radiology tests and medications for patients and sending the results of the tests ordered to the ordering clinicians. It can support transmission of referrals and discharge summaries between clinicians and sharing of appointment scheduling information. Health Level Seven version 2.x is not based on an explicit underlying information model. An information model is important because it is an effective means of documenting assumptions about information and provides a language that allows the unambiguous expression of information in a particular healthcare domain.[23]

2.4.2 Health Level Seven version 3 standard

The Health Level Seven version 3 standard is very different to the Health Level Seven version 2.x standard as it is mostly used for large scale health information systems. At the heart of Health Level Seven version 3 lies a shared information model called the Health Level Seven Reference Information Model (RIM). The Health Level Seven Reference Information Model is a large pictorial representation of clinical data. The Health Level Seven Reference Information Model provides a framework or context for organising data so that it can be delivered and re-used in a variety of different ways and promotes consistency when exchanging information between systems. The various committees in HL7 engage in an iterative consensus process to continually refine the Health Level Seven Reference Information Model to meet its objectives.[24,25]

2.4.3 Health Level 7 Clinical Document Architecture

In addition to creating healthcare messaging standards, HL7 also develops standards for sharing clinical documents between systems. The Health Level Seven Clinical Document Architecture release two was published in 2005. The development of Health Level Seven Clinical Document Architecture was driven by the need for clinical information to be interpreted by both human readers and computer systems. Health Level Seven Clinical Document Architecture supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing.

The standard has been successfully adopted worldwide by healthcare organisations and the industry as a standard to underpin clinical document exchange. It is noteworthy that the industry has embraced the Health Level Seven Clinical Document Architecture standard as implementation is less challenging than the Health Level Seven version 3 standard. This is because the Clinical Document Architecture does not use the entire Health Level Seven Reference Information Model to derive its content and information meaning for document development. Instead, the Clinical Document Architecture is based on a refined information model called the Refined Message Information Models (CDA R-MIM). Health Level Seven Clinical Document Architecture implementation guides describe the use of the standard for a specific document type in a specific context or scenario and can be defined at regional or local level.(26,27)

2.4.4 Health Level Seven Clinical Document Architecture templates

Health Level Seven Clinical Document Architecture is attractive to implementers because it uses a single fixed 'one model and one schema[4]' with well-documented templates that can be reused throughout different types of documents. Health Level Seven Clinical Document Architecture templates are data structures that are used to express a further set of constraints or rules on the Refined Message Information Models (CDA R-MIM). They specify how Health Level Seven Clinical Document Architecture can be used for particular purposes and specific use cases. Clinical Document Architecture templates allow the definition of reusable data structures that can be used across different document types such as clinical summaries, discharge summaries. Clinical information models can map to Health Level Seven Clinical Document Architecture templates (at the section level) and the Health Level Seven Clinical Document Architecture is used as the implementation technology.(28)

[4] In computer science, a schema is created through modelling and is used when talking about both relational databases and object oriented databases. It demonstrates the organisation or structure for a database.

2.4.5 Health level seven Fast Healthcare Interoperability Resources (FHIR) standard

The new generation of Health Level Seven standards is called the Health Level Seven Fast Healthcare Interoperability Resources (FHIR) standard. This standard extracts the best features of Health Level Seven version 2.x, version 3 and the Clinical Document Architecture standard. Thw Health Level Seven FHIR standard enables the secure electronic sharing of health information and the real-time exchange of information using web technologies. The FHIR standard is suitable for use in a wide variety of contexts, including data sharing between electronic health records, mobile phone applications, cloud communications and server communication in large institutional healthcare providers.

The basic building blocks in the FHIR standard are called resources. There are various types of resources defined in the standard, including clinical, identification, workflow, administrative, infrastructure, conformance and financial resources. The philosophy behind the FHIR standard is to build a base set of resources that, either by themselves or when combined, satisfy the majority of common information exchange scenarios in healthcare.

FHIR is based on existing models (clinical, logical and theoretical), and it does not require implementers to understand specific details of the models. FHIR has built-in mechanisms for traceability to the Health Level Seven Reference Information Model and Clinical Document Architecture Refined Message Information Models (CDA R-MIM). This ensures alignment to Health Level Seven's previously defined patterns and best practices without requiring the implementer to have intimate knowledge of the Health Level Seven Reference Information Model.

FHIR was designed to cover a wide range of interoperability scenarios. This includes enabling interoperability between different environments from small clinics within a single institution through to sharing data at a national and international level. It also defines a set of interfaces by which systems actually share information. These four mechanisms for information exchange are known as paradigms and each is a distinct method of exchanging information. The four paradigms and when they might be used are:

- rest — small, light-weight exchanges with low coupling between systems
- messages — communicate multiple resources in a single exchange
- documents — focus is on persistence when data spans multiple resources
- services — use a custom service when capabilities of other paradigms do not fit requirement.

In summary, FHIR has many advantages over other comparable standards and, as the standard reuses modern web technologies software developers are familiar with, it more cost-effective than other standards.[29]

2.5 Other relevant initiatives

Other key initiatives that play an important role in interoperability and clinical information modelling is the Integrating the Health Enterprise (IHE) and the Clinical Information Modelling Initiative (CIMI).

2.5.1 Integrating the Health Enterprise (IHE)

Integrating the Health Enterprise (IHE) is an initiative by healthcare professionals and the industry to improve the way computer systems in healthcare services share information. The initiative aims to enable the seamless and secure access to health information that is usable whenever and wherever needed. IHE promotes the harmonised use of established standards such as Health Level Seven.

The organisation suggests that systems developed in accordance with IHE resources, such as specifications, tools and services for interoperability, communicate with one another better, are easier to implement, and enable healthcare providers to use information more effectively. IHE engages clinicians, health authorities, industry, and users to develop, test, and implement standards-based solutions.

It has established committees to develop and maintain IHE technical specifications on interoperability in areas such as cardiology, information technology infrastructure, pathology and laboratory medicine, patient care devices, pharmacy, quality, research, public health, radiation, radiation oncology, mammography and nuclear medicine. IHE has created a set of information resources and tools for vendors and users of healthcare information systems to help them integrate systems and share information more effectively.[30]

2.5.2 Clinical Information Modelling Initiative (CIMI)

The Clinical Information Modelling Initiative (CIMI) is a Health Level Seven working group that produces detailed clinical information models to enable interoperability of health information systems. It provides a common definition of health information content by defining detailed clinical information models to be semantically interoperable for the purpose of sharing information in electronic health records and documents. The Clinical Information Modelling Initiative models can specify a particular type of data element. For example, a data element could be a laboratory observation, a medical procedure or a heart rate measurement. To date, a modelling methodology, style guide, and a set of models have been established by the Clinical

Information Modelling Initiative. The clinical information models are free for use and there is a repository of models available. The models use a core reference model which bind to different standard clinical terminologies.[31]

2.6 Clinical terminologies

While many systems can achieve technical interoperability (as described in chapter 1), the real challenge is when different health information systems attempt to share clinically meaningful information, that is to say, semantic interoperability. A reference model, data structures and clinical terminologies work together harmoniously, rather than as separate entities, in order to achieve this goal. The interoperability standards that exist to support the collection, use and sharing of clinical information in health information systems include the openEHR archetypes, International Organisation for Standardisation (ISO)/European Committee for Standardisation (CEN) 13606 archetypes, Health Level Seven Clinical Document Archetype Templates, and Health Level Seven Fast Healthcare Interoperability Resources (FHIR) Resources. To achieve true semantic interoperability, the standards need to be used in combination with a clinical terminology such as Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) and Logical Observation Identifiers Names and Codes (LOINC), both of which are described in the following section.

2.6.1 Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)

SNOMED International is a not-for-profit organisation whose main goal is the development of Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), creating a global language for health that enables global healthcare systems to communicate with and understand one another. It develops, maintains, promotes and enables the uptake and correct use of its terminology products in health systems, services and products around the world.

SNOMED CT is a terminology system that can be implemented in computer systems to represent clinically relevant information reliably and reproducibly and is the most comprehensive and precise reference terminology currently available internationally. It covers many aspects of healthcare, including patient histories, details of procedures, and the spread of epidemic disease. It does not attempt to standardise the whole of the medical language nor does it intend that all clinicians should use the same terms.[34] Instead, SNOMED CT attempts to provide a language to adequately reflect the meaning and use of medical concepts.[32,33,34,35]

2.6.2 Governance – SNOMED International

The highest authority in SNOMED Internationl is the General Assembly. It is responsible for ensuring the principles of association, objectives and purpose is followed. The General Assembly has the ability to make binding decisions in relation to SNOMED International, as set out in the Articles of Associations.(36) Responsibilities include strategic planning, budgets and work plans. Two face-to-face meetings are held anually, with some work completed by teleconferencing and through electronic voting. It is not a requirement that all the representatives attend every meeting. Each member is entitled to be represented at the General Assembly. The governance of SNOMED International is set out in the *Articles of Association of the International Health Terminology Standards Development Organisation*.(36)

2.6.3 National release centre

Each member of SNOMED International has a national release centre situated in their respective country. This is the official contact point and has the responsibility for interaction between SNOMED International, affiliates and other member states.(37) The national release centre has a number of responsibilities which includes the receipt of the release of SNOMED CT from SNOMED International. In turn SNOMED CT releases are made available for release in their respective country. The national release centre provides support in terms of the promotion of SNOMED CT adoption and implementation. The national release centres are mainly situated in a national organisation that is responsible for national health informatics and standards in its respective country.(37)

2.6.4 Advisory bodies

SNOMED International has a number of advisory bodies including a members forum and a vendor forum. The Member's Forum is a link between SNOMED International and members who support its objectives. On an operational level, it supports consultation and communication among its member states. Its main functions are in relation to the promotion of shared learning among members, identification of new, proposed products and projects by SNOMED International. It has two co-chairs, one from the Member Forum and one from SNOMED International. The Vendor Liaison Forum provide input into developments, and influence SNOMED CT from a technology and terminologies perspective on topics such as releases and implementation.

2.6.5 SNOMED International Advisory Groups

The advisory groups are led by a member of the management team. The advisory groups involve undertaking work on specific activities. An *Advisory Group Manual*(38) was developed and set out the structures, governance and methods of working. Advisory groups meet as determined by the chair in the schedule and meetings are

held at least quarterly. Terms of reference for advisory groups are in place and the members were appointed by the Chief Executive Officer.[39]

2.6.6 Confluence

Confluence is an online forum for the sharing of information and communication between members of SNOMED International governance and the advisory groups. This facilitates a number of activities around communications, including sharing written material, meetings announcements and information.[40]

2.7 Logical observation identifiers names and codes (LOINC)

An international informatics and healthcare research not-for-profit organisation, the Regenstrief Institute is recognised for its role in improving quality of care, increasing efficiency of healthcare delivery, preventing medical errors and enhancing patient safety. The Regenstrief Institute initiated and continues to direct development of Logical Obeservation Identifier Names and Codes (LOINC), leading the LOINC committee of volunteers from academia, industry, and government who advise and collaborate on its evolution. It is maintained free of charge by the Regenstrief Institute. The Logical Observation Identifiers Names and Codes® name is a registered trademark.

Logical Observation Identifiers Names and Codes (LOINC) version 2.68 was released in 2020. LOINC was developed as a common terminology for laboratory and clinical observations in electronic reports. One of its main goals is to facilitate the communication and grouping of test results for clinical care, healthcare management, and research.[41,42]

2.7.1 Structures and governance

The LOINC committee guides the development of LOINC and its members are volunteers drawn from government, industry and academia. Its mission is to act as the advisory body to the Regenstrief Institute. This work concentrates on the development as well as the distribution of LOINC. It involves the establishment and the development of policies including naming conventions. The members of the LOINC committee serve as subject matter experts and advise the Regenstrief Institute in relation to the development and distribution of LOINC.[43]

2.7.2 Roles and responsibilities of committee members

The responsibilities of the chair involves chairing the LOINC committee and or one of its subcommittees. It also involves coordinating the activities of all the composite committees to achieve the mission of LOINC. The chairs and co-chairs must be members of the LOINC committee. The appointment process for chairs is overseen and operated by a designed authority at the Regenstrief Institute.

LOINC has established a user forum. This forum hosts communication and discussion material on a number of working groups such as special topic workgroups, LOINC development and implementation.[44] Funding was received from a number of organisations, institutes and organisations such as National Library of Medicine.[45]

2.8 International Classifications of Diseases-10

In 1990, the 43rd World Health Assembly adopted the International Classifications of Diseases-10 (ICD-10), it was described as the 'international standard diagnostic classification for all general epidemiological purposes, many health management purposes and clinical use'.[46] It is used in public, primary, secondary and tertiary care for the reporting of health information. It reports on the classifications of diseases, accidents, health encounters, reporting and recording of deaths. It facilitates the storage, organisation and retrieval of clinical diagnostic information. This information is used for analysis of the incidence and prevalence of diseases, as well as the reporting of national mortality and morbidity by WHO member states.[46]

Some of the uses of ICD are:

- epidemiology
- health management
- clinical use
- mortality and morbidity reporting.[46]

The WHO distribute the codes to Member States. A number of revisions were made to the ICD over the years and it is used in over 100 countries worldwide.[47]

2.8.1 Governance structure

The decision-making body of the World Health Organisation is the World Health Assembly.[48] It hosts an annual meeting attended by delegates from each of the Member States. The agenda for the meetings are compiled by the Executive Board and the Health Assembly meet on an annual basis. At this meeting a number of decisions are taken in relation to policies of the organization on such topics as health, appointment of the Director General and oversight of the finances.[48] The governance and management structures for ICD are facilitated through the Collaborating Centres and Family Development Committees established within the WHO [49] and there is a Classifications and Terminologies team in place in the WHO headquarters in Geneva.

2.9 Summary

Chapter 2 summarised the major standards development organisations that develop and publish interoperability standards for health information systems and reflected on the key standards to support clinical information modelling.

The remaining chapters (3-7) in this best practice review will investigate how other countries have approached modelling their health information, the type of interoperability standards they have used and the governance structures they have implemented to support the collection, use and sharing of health information in systems such as the electronic health record and national data collections.

Chapter 3 Australia

3.1 Introduction

Australia has a federal system of government, with a national Commonwealth government, six states and two mainland territories. Powers are shared between federal, state and territorial governments. The powers granted to territories are defined in Commonwealth law which grants them a limited right to self-govern. The federal government has invested significantly to create coherence in Australia's electronic health landscape with a radical shift in digital health policies over the last decade. This includes the establishment of the Australian Digital Health Agency and the move to an opt-out system rather than opt-in system for Australia's national electronic health record, the 'My Health Record'. Australia is considered a forerunner in electronic health developments internationally.(50,51)

3.2 Health and social care system in Australia

With a population of 26 million, Australians have access to comprehensive healthcare, mainly funded through taxation.(52) The Commonwealth government holds the greatest power to raise revenue, with states relying on the Commonwealth to financially support their health systems. Australia's healthcare system is a dispersed network of public and private providers, settings, participants and supporting mechanisms.(53) This makes the Australian healthcare system a complex system with roles and responsibilities divided across different levels of government.(54) Australia has a universal healthcare system called Medicare providing free healthcare to all residents and citizens in the public health system.

While overall coordination of the public healthcare delivery system is the responsibility of federal, state and territory health ministers, the health service in Australia is governed centrally by the Department of Health. Section 3.3 outlines the key organisations in Australia that play central roles in the collection, use and sharing of health information.

3.3 Key organisations

There are a number of key organisations with varying responsibilities in relation to health information. The most relevant for the purpose of this best practice review are the:

- **Department of Health** which has a leadership role in shaping Australia's health and aged care systems through evidence-based policy, targeted programmes and best practice regulation.
- **National Federation Reform Council (NFRC**) In 2020, the Australian Prime Minister announced that the Council of Australian Government (COAG)

will cease and a new National Federation Reform Council (NFRC) would be formed. The NFRC consists of a series of top-level cross-jurisdictional ministerial cabinet committees focused on reform in priority reform areas, including health, tasked to work as cabinet-like groups, rather than as large bureaucratic committees.

- **Australian Health Ministers' Advisory Council (AHMAC)** provides support to the Health Council of the Coalition of Australian Governments (COAG) and considers matters relating to the coordination of health services across Australia; acting as a forum for planning, information sharing and innovation.
- **Australian Institute of Health and Welfare (AIHW)** plays a role in developing and maintaining national metadata standards and providing access to health related data.
- **Australian Digital Health Agency (ADHA) is** tasked with improving health outcomes for Australians through the delivery of digital healthcare systems.

Both the Australian Institute of Health and Welfare (AIHW) and the Australian Digital Health Agency (ADHA) are the organisations of most interest in relation to information modelling. The Australian Institute of Health and Welfare plays a role in developing national metadata standards for national data collections and the Australian Digital Health Agency plays a role in clinical information modelling for the Australian national electronic health record, the 'My Health Record'. A synopsis of the role both organisations play is outlined in section 3.3.1 and 3.3.3 below.

3.3.1 Australian Institute of Health and Welfare

The primary roles of the Australian Institute of Health and Welfare is to collect, analyse and report information drawn from health, community and housing assistance services. The Australian Institute of Health and Welfare also develops and maintains national metadata standards and provides access to health-related data.[55] It is the statutory body that serves as custodian of the majority of national health and welfare data collections in Australia. The Australian Institute of Health and Welfare contributes to the health and medical research effort in Australia by analysing data on health and health services, making data holdings available to researchers, supporting researchers with data integration services, and developing and promoting information standards for the health sector. Much of the data that the Australian Institute of Health and Welfare reports at national level is received from state and territory government departments.

3.3.2 Data collections managed by the Australian Institute of Health and Welfare

The Australian Institute of Health and Welfare managea national health and welfare data collections. These collections are primarily administrative data collections

operated by the state and territory government departments. The Australian Institute of Health and Welfare operates a central register of its data holdings with a catalogue of these data holdings accessible online. States and territories routinely remove identifying information from datasets before submitting data to the Australian Institute of Health.

3.3.3 Australian Digital Health Agency

The Australian Digital Health Agency, commenced operations on 1 July 2016, and is tasked with improving health outcomes for Australians through the delivery of digital healthcare systems and leading the development of the *National Digital Health Strategy* and its implementation framework. It was established as a statutory authority in the form of a corporate Commonwealth entity and the Australian Digital Health Agency reported to State and Territory Health Ministers through the Coalition of Australian Governments (COAG)[56] Health Council, now replaced by the National Federation Reform Council (NFRC). The Australian Digital Health Agency is responsible for national digital health services and systems, with a focus on engagement, innovation and clinical quality and safety.

3.3.4 National Digital Health Strategy

In 2017, the Australian Digital Health Agency consulted on and then delivered the *Australian National Digital Health Strategy (2018-2022)*.[6,57] The Strategy proposes seven strategic priority outcomes to be achieved by 2022. The purpose of this strategy is to provide a clear plan to achieve better health outcomes in Australia. The seven priorities are the 'My Health Record' system, secure messaging, interoperability and data quality, medication safety, enhanced models of care, workforce education, and driving innovation. The goals of the *Australian National Digital Health Strategy (2018-2022)* include better care coordination and fewer preventable hospitalisations, improved self-care, reduced duplication and operating costs, and improved patient and provider experiences.

3.4 eHealth development in Australia

Australia ia considered pioneers in ehealth internationally. Since 2005, the Commonwealth, states and territories have been investing in key building blocks for a national electronic health platform. Key electronic health projects that are operational in Australia include the:

- National health identifier — individual healthcare identifiers (IHI) are in place in Australia (only for the My Health Record)
- My Health Record — Australia's national electronic health record is also used by patients to access their health information (patient portal)
- electronic prescribing was first introduced in early 1990s

- electronic referrals are in place and linked to the My Health Record system.[54]

3.4.1 Overview of electronic health systems in Australia

The national health identifier, My Health Record, electronic prescribing and electronic referrals Australia are outlined in the following section.[54]

National health identifier

Healthcare identifiers were introduced in 2010 as the foundation for digital health in Australia and as a building block for the My Health Record system. The healthcare identifiers service is a national system for uniquely identifying individuals and healthcare providers. Individual healthcare identifiers are automatically assigned to all individuals registered with Medicare Australia or enrolled in the Department of Veterans' Affairs (DVA) programmes. This number is then validated by the healthcare identifiers service operator and becomes their unique individual healthcare identifier. There is no option to opt-out of the individual healthcare identifier.

My Health Record

The 'My Health Record' system is the Australian government's electronic health record system created for every individual in Australia in January 2019, unless an individual opted out in advance. It contains online summaries of individuals' health information including: hospital discharge summaries, reports from test and scans, such as blood tests, prescribed medications and referral letters.

Electronic prescribing

Recent changes in 2020 have been made to Commonwealth legislation to recognise an electronic prescription as a legal form to allow supply of medication. Paper prescriptions are still available and patients can still choose which pharmacy they attend to fill their prescription. The vast majority of community medical prescriptions in Australia continue to be delivered on paper, either in printed or hand-written format. Electronic prescription in Australia is currently provided by two service providers, MediSecure and eRx. Both services can be integrated into many of the existing clinical and pharmacy prescribing software systems.

Electronic referrals

The My Health Record system supports electronic referrals. When a healthcare provider creates an electronic referral, it is sent directly to the intended recipient. A copy is also sent to the My Health Record system. Electronic referrals can be sent and received directly between healthcare

providers (point-to-point), through secure messaging, and or uploaded to and retrieved from a patient's My Health Record (point-to-share).

3.5 Interoperability

In Australia, interoperability or health data exchange is performed using Health Level Seven version 2.4 messaging or the Health Level Seven Clinical Document Architecture standard. The My Health Record primarily uses the Health Level Seven Clinical Document Architecture standard. In addition, it has a read-only Health Level Seven Fast Healthcare Interoperability Resources (FHIR) interface. Health information exchange is used for pathology and imaging results, electronic referrals, clinical reports and letters and discharge summaries. If electronic exchange is not possible, discharge summaries are exchanged through fax or email. Prescription exchanges operate using application programming interface (APIs).[5] Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) has been endorsed by the Australian state and territory governments and identified as the preferred national clinical terminology, with Logical Observation Identifiers Names and Codes (LOINC) used for pathology requests and results.(6)

The Australian Digital Health Agency developed an *Interoperability Frameworkv2.0* which is a common reference point that provides guidance to business and information technology (IT) experts in delivering interoperable eHealth systems in Australia. The framework defines interoperability from an organisational, information and technical perspective as described in Chapter 1.(5)

3.6 Information modelling

Across Australia's healthcare system, information modelling in healthcare occurs at local, jurisdictional, and national levels developed by government, vendor, standards groups, and other players for different use cases. Information models are developed on a use case[6] by use case basis. Over the last 15 years, all electronic health projects have used logical information models. Projects built on logical information model include:

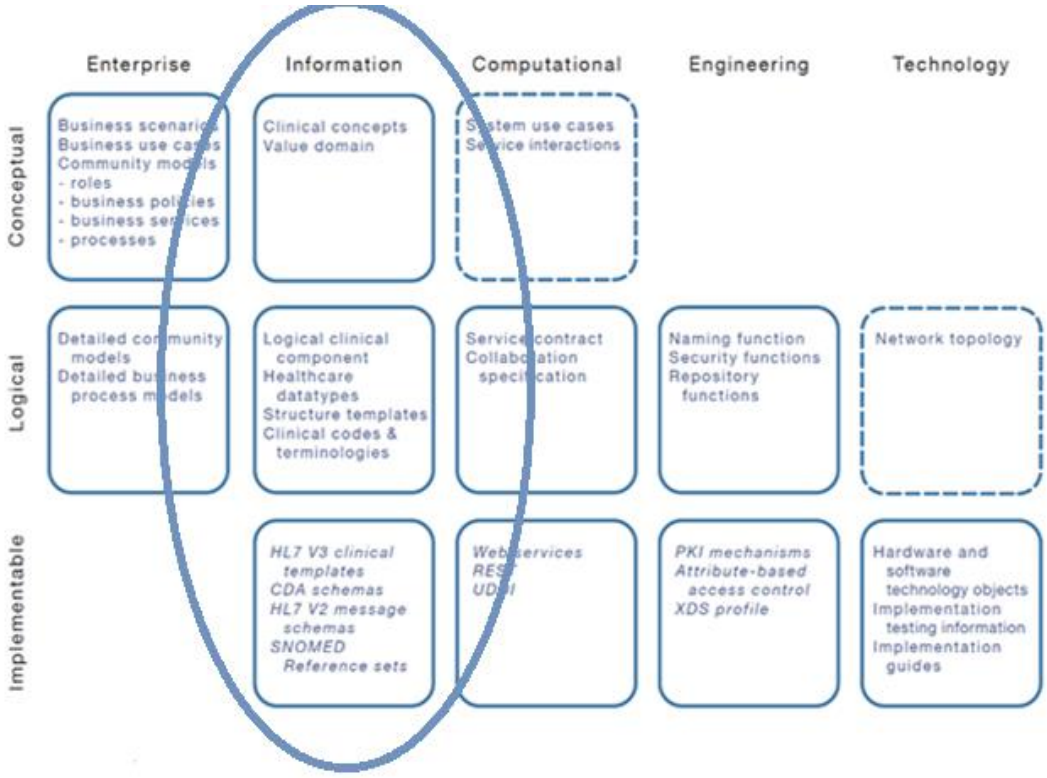
- exchange of clinical records: referrals (healthcare-specific and wider community services), aged care transfers, pathology reporting and requests, diagnostic imaging reporting and requesting, electronic prescribing and exchange of records of prescriptions and dispenses, medicines lists, discharge summary, advance care plans, and health summaries (allergies, medicines, medical history)

[5] An API is a software intermediary that allows two applications to talk to each other. Each time you use an app like Facebook, send an instant message, or check the weather on your phone, you're using an API.
[6] A use case is a written description of how users will perform tasks on a system. It outlines, from a user's point of view, a system's behaviour as it responds to a request. Each use case is represented as a sequence of simple steps, beginning with a user's goal and ending when that goal is fulfilled.

- Australian register information, for example, Australian Organ Donor Register
- immunisation register
- pathology test result
- government reporting of healthcare data.

There are many different information models used, depending on the scope of the project and the jurisdiction that they are being developed in. There is a single framework (Figure 6) within which different information models are adopted for different purposes and scopes of use. This framework spans enterprise, information, computational, engineering and technology areas, outlining how the various types of models from conceptual through to clinical information models work together to enable interoperable solutions across Australia. For the purpose of this review, the conceptual, logical and implementation information level is of most interest. At the conceptual information level, there is an option to design clinical concepts and include values associated with concepts. At the logical information layer, there are more rules or constraints applied to the concepts and clinical terminologies and data types are introduced. The implementation information level outlines the choice of technical standards that can be used to implement the clinical information models.

Figure 6 – Framework structure populated with modelling constructs



3.6.1 Clinical information models for electronic health projects in Australia

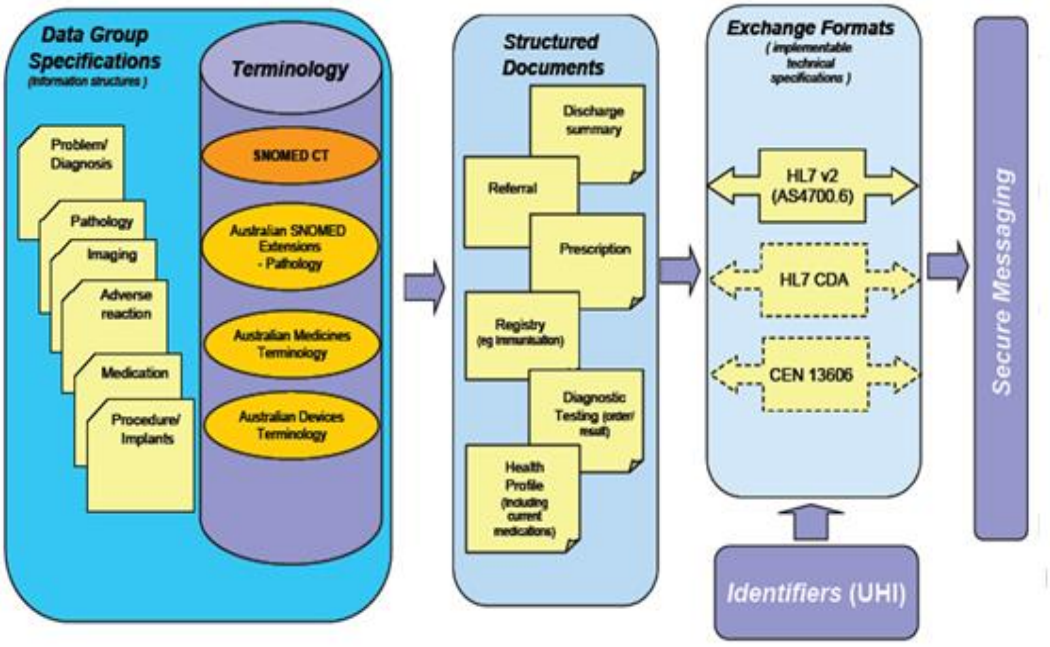
As outlined in section 3.4.1, the My Health Record is a national online patient summary which collects information from various registered healthcare providers.

Some types of documents that are included in this repository, called the 'data groups specifications library', are: shared health summaries, electronic referrals, specialist letters, discharge summaries, event summaries, prescription and dispense records, and diagnostic imaging and pathology reports.

The Digital Health Australia Agency have modelled health information for the My Health Record by creating detailed clinical logical models. Examples of detailed clinical logical models in Australia range from problem/diagnosis, adverse reaction, medication order and blood pressure. There is a library with a suite of the detailed clinical logical models and the latest release of this library was published in 2017.[58]

Detailed clinical logical models provide descriptions for clinical content used in different clinical scenarios the Digital Health Australia Agency use the openEHR archetypes as the conceptual basis for their clinical logical models and the Health Level Seven Clinical Document Architecture.

Figure 7 Clinical information models (taken from Digital Health Australia Agency)



3.6.2 Health Level Seven

Australia has recently changed direction and transitioned to using Health Level Seven Fast Healthcare Interoperability Resources (FHIR) as their detailed clinical logical models. As part of the transition to FHIR, the Digital Health Australia Agency has introduced a process to develop FHIR profiles in a collaborative, open and transparent process in partnership with standards organisations and industry. It has invested heavily in a partnership with Health Level Seven Australia.

3.6.3 National Health Data Dictionary

In 2003, the Australia Institute of Health and Welfare published a report on a national health information model (version 2) which described an enterprise-wide — covering all of healthcare — conceptual model.[58] This model is still in use in Australia within its intended purpose and scope, that is it underpins the National Health Data Dictionary. The National Health Data Dictionary provides national standards for the broader health sector. The data dictionary is based on METeOR, Australia's repository for national metadata which is an online metadata registry for developing, registering and disseminating metadata based on the second edition of the international standard ISO/IEC 11179 Information Technology-Metadata registries in 2003 (ISO/IEC 11179:2003). METeOR is an Internet-based application accessible through its web address.[59]

3.7 Governance

3.7.1 My Health Record

The Digital Health Australia Agency assumes governance responsibilities for all digital health strategy, design, development, delivery and operations and functions. It is also the My Health Record system operator. The Department of Health has retained responsibility for national digital health policy and certain parallel activities. The Commonwealth Minister for Health has the authority to make the My Health Record's rules, which set out operational details to support the My Health Record system. The Minister must consult with the system operator and a subcommittee of the Council of Australian Governments (COAG) Health Council before My Health Records rules are made.[54]

3.7.2 Interoperability standards

The healthcare messaging industry worked as a subgroup of Standards Australia from late 1990s to approximately 2015. It was focused on pathology and patient administration messaging, though the standards developed also covered diagnostic imaging. The Health Level Seven version 2.x standard was used as it was the primary messaging standard at the time. The structure of the committees in both Standards Australia and Health Level Seven Australia are similar, with two co-chairs and an open invitation to industry stakeholders. In the case of Standards Australia, the developed documents were put out for review and refined in the review process. Health Level Seven Australia follows the same process as Health Level Seven International where the Australian localisation of standards is released for feedback to the community. The feedback is used to refine the document. In terms of information modelling, different information models are governed by different parties – each has their own mechanism depending on the use case or project that is being developed.

Generally, vendors play a role in working groups (including Health Level Seven, Health Level Seven Australia and Standards Australia). Vendors can play a significant role in the committee, where one Health Level Seven Australia committee co-chair is a messaging vendor, some vendors have staff contribute to a specific committee. However, the majority of vendors tend to wait until a standard document is produced and is available for review. Vendors may not be enabled to play a role in some programmes of work, or in some cases may be heavily involved in the majority of decision-making as in the recent secure message proof of concept projects.

3.7.3 National Health Data Dictionary

The National Health Data Dictionary is an initiative under the National Health Information Agreement. Under these agreements, all parties agree to ensure that the collection, compilation and interpretation of national information are appropriate and carried out efficiently. This requires agreement on definitions, standards and rules for collecting information, and on guidelines for coordinating the access, interpretation and publication of national community services and health information.

3.8 Clinical Terminologies and Classifications

3.8.1 Classifications - Independent Hospital Pricing Authority

In December 2011, the Independent Hospital Pricing Authority was established under the National Health Reform Act 2011.[60] It is an independent agency that resulted from the National Health Reform Agreement[61] by the Council of Australian Governments. The National Health Reform Agreement is an agreement between the Australian Government and all state and territory governments. It commits to improving health outcomes for Australians by providing better coordinated and joined up care in the community, and ensuring the future sustainability of Australia's health system. One of the Independent Hospital Pricing Authority's roles involves the national efficient pricing of the public hospital services and activity based funding. From 1 July 2019, the development of ICD-10-Australian Modifications, Australian Classifications of Health Interventions and the Australian Coding Standards (ACHI/ACS)[62] was brought under the remit of the Independent Hospital Pricing Authority.

The chair of the Independent Hospital Pricing Authority reports to the Minister for Health. The day-to-day management and responsibility for the Independent Hospital Pricing Authority responsibility is held by the Chief Executive Officer (CEO). It has eight teams divided into two sections:[63] the Policy Section and Classification and Data Analytics Section.[63] The Classification and Data Analytics Section works with a number of stakeholders including technical, clinical and jurisdictional to develop and maintain the clinical classifications, business rules and coding standards for implementation of the national activity based framework in public hospitals. The

section is also responsible for the introduction of new classifications, not in existence under the National Health Reform Act 2011.[60]

3.8.2 Clinical Terminologies SNOMED CT

The National Clinical Terminology Service is managed by the Australian Digital Health Agency. It is responsible for clinical terminologies as well as tools and services that provide support for the development, distribution and management of national clinical terminologies. The National Clinical Terminology Service is the National Release Centre for SNOMED CT-AU in Australia. AU is the extension for Australia and is released monthly. [64]

The formal governance structures for SNOMED CT-AU consists of a representative from the Australian Digital Health Agency reporting to the General Assembly in SNOMED International. In 2016, the Australian Digital Health Agency established a formal agreement for the use of clinical classifications set out in the *Australian National Terminology Licence Agreement.*[65] National support groups were established consisting of the Australian Clinical Terminology User Group and the Australian Medicines Terminology Support Group.

3.8.3 Australian Clinical Terminology User Group

The Australian Clinical Terminology User Group is a national forum for the terminology community. The user groups comprise of users, developers and implementers and is self-governing meeting on a quarterly baisis.[66]

3.8.4 Australian Medicines Terminology

The Australian Medicines Terminology was developed to standardise the identification of medication. As SNOMED CT-AU is the national terminology for use in Australia, the Australian Medicines Terminology was integrated into it.[67] The Australian Medicines Terminology provides unique codes for all medication that is available to healthcare professionals in Australia. This is an essential requirement for digital health, and in particular for the implementation and use of clinical systems in Australia. These systems support the prescribing, dispensing, administering, recording of electronic medication management.[68]

3.8.5 Australian Medicines Terminology Support Group

The Australian Medicines Terminology Support Group members comprise computer system vendors, clinicians and representatives from all the states and territories in Australia. Members meet on a regular basis and provide expert advice and guidance in relation to any issues on the medication terminology. Membership of the support group is an open forum in which individuals have the opportunity to be included in any new developments.[69]

3.9 Key learnings

- Australia is considered a forerunner in eHealth internationally and has a high level of maturity regarding their eHealth systems and national data collections.
- There is robust governance of eHealth services and national data collections with strong leadership and clear organisational responsibility for governing health information at a national level and in territories in Australia.
- There is substantial political will and investment in eHealth developments.
- Australia has a long and significant history of modelling health information. In 2003, the Australia Institute of Health and Welfare published a report on a national health information model (version 2) which described an enterprise-wide model (or conceptual model) covering all of healthcare. However, this model was not fully implemented and it developed a suite of logical information models for use in the national electronic record – the 'My Health Record'.
- There are many different information models used, depending on the scope of the project and the jurisdiction that they are being developed in.
- Australia has a framework to help implementers design information models and implement them with appropriate standards.
- Australia has a long history with health data exchange or interoperability.
- Australia has recently changed direction and transitioned to using Health Level Seven Fast Healthcare Interoperability Resources (FHIR) resources replacing their detailed clinical logical models approach.
- The National Health Data Dictionary is based on METeOR, Australia's repository for national metadata based on the ISO/IEC 11179 data model.

Chapter 4 Canada

4.1 Introduction

Canada's population of approximately 34 million people is governed as a constitutional monarchy with a federal system of government, consisting of 10 provinces and three territories. As a federal state, roles and responsibility for the delivery of healthcare is largely divided between the federal, provincial and territorial governments.[70,71] The federal government also has important responsibilities in public health, health research and health data collection. Canada's publicly-funded healthcare system, known to Canadians as 'Medicare', is financed through federal, provincial and territorial taxation. Nearly all healthcare providers are private.[72]

Advancing the electronic health agenda has been a key deliverable in Canada for several decades. Since 1990, Canada has been working on the development of a national health information system infrastructure through a series of roadmaps. Canada has implemented a number of information systems for the collection, reporting and analysis of health data (national data collections) and has established a pan-Canadian blueprint to support the development of what it terms, interoperable electronic health record (interoperable EHR).[73] Due to the high level of decentralisation in Canada, provinces have power over administration and governance of their health systems. Therefore, electronic health agencies provide leadership and deliver electronic health solutions in their respective jurisdictions.[74] Due to the high level of decentralisation in Canada, provinces and territories govern their own electronic health agencies which provide leadership and deliver electronic health solutions in their respective jurisdictions.[74] Hence, this review also covers electronic health developments, interoperability standards, information architecture and information modelling that is ongoing in the Canadian province of Ontario.

4.2 Key organisations

The two most relevant organisations in Canada, with varying responsibilities regarding health information systems (electronic health and national data collections) are Canada Health Infoway (Infoway) and the Canadian Institute for Health Information (CIHI) respectively. Each organisation is described in the following sections.

4.2.1 Canada Health Infoway

Canada Health Infoway (Infoway) was established in 2001 as an independent, not-for-profit organisation, funded by the federal government. It has the mandate to provide investment and support for the development of pan-Canadian electronic

health record infostructure to significantly advance the use of eHealth in Canada.[75,76] Canada Health Infoway describes an infostructure as 'a shared foundation of hardware, software, and communication technologies with associated architectures that enable an uninterrupted flow of information'. Canada Health Infoway works with partners to strategically invest, support and accelerate the development and use of electronic health in Canada.[74] Partners include federal, provincial and territorial governments and various industry stakeholders — such as, technology vendors, provincial electronic health agencies, industry associations and healthcare organisations.

The most recent *Canadian health strategy, 2015: Advancing the Next Generation of Health Care in Canada* is a roadmap for advancing Canada Health Infoway infostructure, investments and priorities. An incremental and phased approach was taken to complete the infostructure. While good progress is evident in some jurisdictions, particularly in the area of health interoperability standards, it has been slow to progress and somewhat inconsistent in other jurisdictions. Projects first completed across all jurisdictions were the public health surveillance system, identifier registries and diagnostic imaging, with drug, laboratory and the interoperable electronic health record making less progress.[77]

Infoway is accountable to its Board of Directors and Corporation Members. The members of the Corporation are deputy ministers of health from across Canada's 10 provinces, three territories and the federal government.[78] Infoway is the National Release Centre for SNOMED CT CA, pan-Canadian LOINC and Health Level Seven.[79]

Standards centre

Infoway has established a standards centre which provides access to international and Canadian health information standards. Some of the standards include:

- SNOMED CT
- SNOMED CT CA
- LOINC/pCLOCD
- Canadian Clinical Drug Dataset
- ICD-10-CA
- Health Level Sevem FHIR
- Digital Imaging and Communication in Medicine
- Ambulatory Treatment Centre
- Nursing Data Standards.

However, Infoway is transitioning towards more product-based solutions and away from interoperability and standards.[79]

4.2.2. Canadian Institute for Health Information

While Canada Health Infoway has the mandate to accelerate uptake of electronic health in Canada, the Canadian Institute for Health Information (CIHI) has the

mandate to deliver 'comparable and actionable information to accelerate improvements in healthcare, health system performance and population health across the continuum of care'.[74] Canadian Institute for Health Information is an independent, not-for-profit organisation that plays the most significant role in the overall management of national data collections and is the national organisation that collects, analyses and disseminates information on Canada's healthcare system. The Canadian Institute for Health Information is accountable to the federal government, providing a leadership role in coordinating a common approach for health information in Canada. Its stakeholders use a broad range of health databases, measurements and standards, together with evidence-based reports and analyses, in day-to-day decision-making.[76]

The Canadian Institute for Health Information was led by a board of directors of 16 members. The Board of directors were responsible for governance of the Canadian Institute for Health Information, measurement of indicators of success and the responsible use of resources. The Canadian Institute for Health Information had developed a *Board of Directors Governance Handbook, 2018*.[80] The Board had another function as the National Coordinating Council in Canada for Health Information. It connected non-governmental groups interested in health related matters with territorial, provincial and federal governments.

4.2.3 Data collections managed by the Canadian Institute for Health Information

Each of the 30 data collections are listed on the Canadian Institute for Health Information website — www.cihi.ca — with details provided on the type of care each collection relates to. Specific information is also provided at the individual data holding level, including data source, coverage, availability, classification, data elements and the annually published data quality reports. Support is available to clients of Canadian Institute for Health Information, for example, clients can use the eQuery Tool to search an existing repository of questions and answers on data-related topics.[81]

4.3 Interoperability

In 2003, Canadian Institute for Health Information and Canada Health Infoway began working in partnership to develop and maintain standards required for the introduction of the electronic health record data definitions. The Canadian Institute for Health Information promotes the development of health information management standards such as coding classification, management information system standards (MIS Standards), data dictionary and infostructure standards. This is a crucial role in ensuring that comparisons between and or within health jurisdictions are consistent and meaningful for such activities as health system

planning and programme development. They have recently published the Canadian Institute for Health Information Reference Data Model (CRDM), a data model underpinning the national data dictionary which is outlined in more detail below.

Currently, clinical, administrative, drug, and diagnostic data are exchanged provincially, territorially and federally. Methods of data exchange vary and include the use of Health Level Seven version 2.x messages, Health Level Seven version 3 messages, the Health Level Seven Clinical Document Architecture (CDA) standard, the Health Level Seven Fast Healthcare Interoperability Resources (FHIR) standard and Integrating the Health Enterprise (IHE) profiles.

Canada Health Infoway provides 100% of the funding required for the development of messaging, terminologies and interoperability standards. There is a dedicated team to liaise with international health-related standards development organisations, such as Health Level Seven. Canada has an extensive track record with involvement in Health Level Seven and is well represented on Health Level Seven technical committees. Canada also contributed to the work to evolve the Health Level Seven messaging standards from version 2.x to version 3.[74]

Canada Health Infoway has developed an electronic health record blueprint which details the vision and direction for the delivery of electronic health to support an interoperable electronic health record throughout Canada. This involves the development of an 'information and interoperability' framework or architecture to support the development of solutions for sharing healthcare information throughout Canada. The blueprint allows the jurisdictions and Canada Health Infoway to work together to align electronic health record initiatives with a common, pan-Canadian architecture, as well as common standards for semantic interoperability.[74] The purpose of the electronic health record blueprint is to provide the conceptual framework and working principles for development of shareable electronic health records across the country.

4.3.1 Classifications and terminologies in Canada

The Canadian Institute for Health Information is responsible for clinical classifications, setting the standards for morbidity across Canada and supporting all requirements for ICD-10-CA. These responsibilities included the distribution, maintenance, provision of training and development of standards. Some of the clinical classifications used include:

- ICD-10-CA
- Canadian Classification of Health Interventions
- The International Classification of Functioning, Disability and Health.[82]

4.3.2 Classifications and Terminologies Team

In 2018, the Canadian Institute of Health Information employed over 700 members of staff. There is a dedicated Classifications and Terminologies Team in place. Some of the work the team completed included reviewing ICD-11 for the WHO.[83]

A number of the roles include:

- Manager Classifications and Terminologies Development
- Project Lead Classifications and Terminologies
- Canadian Institute for Health Information specialists.

4.3.3 Governance of clinical classifications and terminologies

Canada had established formal governance structures for clinical classifications and terminologies. There are two organisations responsible at a national level for clinical terminologies and classifications. The Canadian Institute for Health Information is responsible for for classifications and Canada Health Infoway is responsible for clinical terminologies.

The governance structures in Canada Health Infoway include a Board of Directors and corporation members. Members of the corporation were drawn from the deputy ministers of health from across Canada's 10 provinces, three territories and the federal government.[78] Canada Health Infoway is the National Release Centre for SNOMED CT CA, pan-Canadian LOINC and Health Level Sevem.[79] The Canadian edition of SNOMED CT is known as SNOMED CT CA. Canada Health Infoway is the Canadian representative to SNOMED International and has SNOMED CT Canadian national release licence agreements in place. It has also established the Health Terminology Community. This facilitates learning about classification systems, health related terminologies and terminology subsets.

Canadian Institute of Health Information works with the Collaborating Centre for Family of International Classifications in America. Staff from Canadian Institute for Health Information serve on the committees, reference groups and hold voting rights. These committees and references groups meet on an annual basis at the WHO-Family of International Classifications Network meetings.[83]

4.3.4 SNOMED CT CA

The Canadian Edition of SNOMED CT is known as SNOMED CT CA. This extension was developed and modified specifically for use in Canada. Infoway is the national release centre for SNOMED International and is the Canadian representative to SNOMED International.[84] In Canada, SNOMED CT CA is released twice yearly in March and September. There are formal process in place for change requests and these are facilitated in both English and French.

4.3.5 InfoCentral Health Terminology Community

Infoway has established a Health Terminology Community. This is a facility to learn and share learning about classification systems, health related terminologies and terminology subsets. The learning includes updates, implementation of new or existing classifications and terminologies.(85)

4.3.6 Pan-Canadian LOINC

Infoway is also the national release centre for pan-Canadian LOINC which is the Canadian version of LOINC. This version includs Canadian names and units of measurement as recommended for use in Canada.

4.4 eHealth developments in Ontario

As mentioned, due to the high level of decentralisation in Canada, provinces and territories govern their own electronic health agencies which provide leadership and deliver electronic health solutions in their respective jurisdictions.(74) Hence, this review covers electronic health developments, interoperability standards, information architecture and information modelling that is ongoing in the Canadian province of Ontario.

Ontario is one of the 13 provinces and territories of Canada and is located in east-central Canada. Ontario has a population of over 14 million. Electronic health Ontario's mandate is to implement a system that, in addition to providing an electronic health record for every Ontarian, includes a data network that stores electronic health record data and makes it quickly and securely available to healthcare providers.

The electronic health environment in Ontario is complex: Ontario has approximately 300,000 healthcare professionals — such as family doctors, specialists, pharmacists, and imaging technicians — who care for almost 14 million people. As well as that, multiple individual local electronic health systems (known as point-of-care systems) that store health information already exist.(86)

4.4.1 Electronic health record

Currently, patients do not have access to their own health record in Ontario. After addressing early challenges, the foundation of the patient's electronic health record now exists and the majority of what Ontario considers the 'core electronic health record systems' have been developed, and information in these systems is being shared among authorised healthcare professionals. Core electronic health record systems include the:

- Ontario Laboratories Information System
- Diagnostic Imaging System, including the central and regional repositories
- Diabetes Registry
- Drug information system (now called the Digital Health Drug Repository)
- Community-based physicians' Electronic Medical Records
- Integration services project (work required for connectivity of various information systems; now called the Connecting Hubs).[87]

4.4.2 Health Identifier, electronic prescribing and electronic referrals

In addition to the electronic health record, the key eHealth initiatives in use include health identifiers, electronic prescription service (electronic prescribing) and electronic referrals. An overview of each is briefly outlined below.

Health identifiers

Eligible residents in the province of Ontario may apply to receive provincially-funded health services covered by the Ontario Health Insurance Plan. A health card is issued by the Government of Ontario to the insured person. A unique 10-digit permanent identification number and a version code, together known as the health number, are assigned to eligible residents.[86]

Electronic prescribing

Electronic prescribing has not yet been fully deployed in Ontario. However, PrescribeIT, a national not-for-profit electronic prescribing service for community prescribers in Canada is now also available in Ontario. Physicians and pharmacies in Ontario use PrescribeIT. This is the first national data exchange service, with Fast Healthcare Interoperability Resources (FHIR) based integration to prescriber's electronic medical records, pharmacy management systems, and interoperability with registries and databases managed by the provinces and territories. This is the first time that Canada Health Infoway has taken the role of directly managing a digital health service.[88]

Electronic referrals

The Ocean electronic referral network is an electronic health record-integrated, cloud-based technology for healthcare referrals developed by CognisantMD. The network includes a map-based, searchable directory of healthcare providers with wait times, intelligent referral forms, end-to-end reporting, and automated status alerts for patients and providers. Using Ocean's secure, online electronic referral directory, healthcare providers can search for specialists and patient programmes, view wait times and locations,

and create and submit a healthcare referral in real time. With integrated electronic health records, referrals are sent, tracked and updated right from the patient's chart.[89]

4.5 Information Architecture in Ontario

eHealth Ontario has developed, in collaboration with key stakeholders, electronic health conceptual information architecture. The conceptual information architecture is a high-level view of what information is found in an electronic health record in Ontario, providing broad guidelines on how that information should be structured. It is intended for use by all authorised stakeholders for electronic health records in Ontario, including but not limited to eHealth Ontario, the Ministry of Health and Long-Term Care, healthcare providers, patients and vendors. As stated in the Conceptual Information Architecture specification, it provides:

- common vocabulary to facilitate communication and coordination between parties within electronic health Ontario and across the broader electronic health environment
- an information structure to guide the planning, design, and data integration of electronic health record systems
- a map of information relevant to the business that serves as the basis for information management and governance
- conceptual information model (CIM) diagrams and definitions.

4.6 Information modelling in Ontario

There are various information models used throughout Canada underpinning electronic health projects. Different information models are used for different use cases. For example, eHealth Ontario has used a conceptual information model for the design of its electronic health record which is based on industry standards adapted to reflect Ontario's healthcare requirements and priorities. It has also developed a data model that underpins the national data dictionary for national data holdings, managed by Canadian Institute for Health Information. Both models are described throughout the following sections.

4.6.1 Ontario's Information model for provincial electronic health record in Ontario

eHealth Ontario developed and released a Blueprint in 2015 that provides a high-level view of the various modules of an electronic health record. Ontario adopted the Canada Health Infoway reference blueprint, described in section 2.4 above. Underpinning the interoperable electronic health record is the 'information viewpoint architecture' which provides an information model for an electronic health record in Ontario. It offers a structure for managing health information from multiple sources.

The view defines each piece of information to support a common language between electronic health record stakeholders, and identifies what information about a patient is collected, included, and expected at any point in the healthcare system.(73)

4.6.2 Governance of the provincial electronic health record in Ontario

Facilitated by eHealth Ontario, four provincial committees have been established to meet the broader needs of governance in key areas. With membership including subject matter experts from interest groups across the province, committee members engage their constituents to ensure that decisions and direction are informed by the broader health care community. The Ontario electronic health record architecture and standards business and technical and strategic committees are advisory and approval bodies:

- The business and technical committee for provincial architecture and standards products, services, policies, and processes, and
- The strategic committee for providing direction on how electronic health record connections should be established.

These committees, comprised of representatives from 23 healthcare organisations across the province, provide a forum to involve key healthcare stakeholders in architectural and standards decisions, thereby increasing support in the community, and helping overcome adoption barriers.

The Ontario Ministry of Health Long-Term Care (MOHLTC) is responsible for establishing an electronic health record governance body that sets strategic investment priorities in alignment with broader public sector objectives. This will directly inform strategic planning at all levels, leading to more effective utilisation of provincial resources and a more focused approach to realise the provincial electronic health record.

These governance bodies, along with their respective mandates, frameworks, and policies, must be integrated to align with and support one another. Having an effective provincial electronic health record governance model, where all stakeholders are clear on decision authority and accountability, is essential to achieving a unified, cost-effective, high-quality, safe, private, and secure provincial electronic health record.(90)

4.6.3 Information model for the provincial electronic referral system in Ontario

eHealth Ontario has published a report on the provincial electronic referral 'Conceptual and Information Architecture'. The conceptual architecture is firstly designed to support the referral pathways and secondly a conceptual information

model (CIM)[7] to assist in identifying the concepts (common categories of information) required for exchange between electronic referral systems. The electronic referral CIM is derived directly from the latest version of the electronic health blueprint conceptual information model as outlined in 4.6.1 above, which is the overarching information model for the provincial electronic health record. The electronic referrals CIM includes a high-level business overview, business requirements, supporting information architecture and deployment priorities. It is recommended that projects using the provincial electronic referral strategy collaborate to create and follow a single logical data model (LDM) for electronic referral solutions.(90)

4.6.4 Governance on the provincial electronic referrals project

As described in section 4.6.2, the same governance structure is in place for the provincial electronic referrals project. The Ontario electronic health record architecture and standards governance committees, consisting of the strategic committee and the business and technical committee, have provided tangible benefits for the province since their formation in 2012 under the guidance of the Ministry of Health Long-Term Care (MOHLTC) Action Plan for Health initiative. They provide both advisory and approval for provincial architecture and standards products, services, policies, and processes, and provide strategic direction for how electronic health record connections are established.(90)

4.7 Canadian Institute for Health Information Reference Data Model (CRDM)

The Canadian Institute for Health Information (CIHI) Reference Data Model (CRDM) standard is a standardised, high-level, corporate-wide reference data model. It is a standard that enables data integration and semantic interoperability for national data holdings. The Canadian Institute for Health Information Reference Data Model (CRDM) identifies:

- Concepts (categories of data) such as a person, thing, place or event
- Relationships between the concepts
- Core attributes — key information about each concept.

The Canadian Institute for Health Information (CIHI) Reference Data Model (CRDM) contributes to Canadian Institute for Health Information's (CIHI's) goal of semantic interoperability (that is to say, common terminology and meaning) and data integration to provide the following benefits:

[7] A **Conceptual Information Model** is a high level diagram describing the important information in an enterprise or system; it is typically useful for communicating ideas to a wide range of business and technical stakeholders. ... The diagram typically consists of named entities and their relationships to each other.

- 'Better meet the needs of current and future analyses and reports by facilitating data integration across the continuum of care
- Support the use of health information in health system decision-making
- Provide the possibility to use the electronic health record (electronic health record) as a source of data in the future through alignment with electronic health record standards and
- Reduce development and maintenance costs for application systems and data assets'. (91)

4.7.1 Governance of the Canadian Reference Data Model

Use of the Canadian Institute for Health Information (CIHI) Reference Data Model (CRDM) is documented by the CIHI Reference Data Model (CRDM) Team in consultation with the Project Team. This feedback directly influences the evolution of the CRDM. For example, if several projects are not able to use a CRDM concept definition without substantially changing the meaning, a review of that concept definition may be necessary. This iterative, bottom-up top-down approach to maintaining the model uses the lessons learned from each project to ensure that the CRDM continues to reflect CIHI's changing business needs.(91)

4.8 Key learnings

- Canada is considered a leader in eHealth internationally.
- There is a high level of maturity regarding its eHealth systems and national data collections.
- There is strong leadership and clear organisational responsibility for governing health information at a national level and throughout provinces in Canada with separate national organisations responsible for eHealth developments and national data collections.
- There is strong governance structures in place to ensure successful interoperability of health information systems in the province of Ontario with four provincial committees established to meet the broader needs of governance in key areas in eHealth.
- There are various information models used throughout Canada underpinning eHealth projects and national data collections. Canada has an overarching conceptual model for the development of their interoperability electronic health records that each province can reference to implement

provincial electronic health records. The Canadian Institute for Health Information have recently published the Canadian Reference Data Model (CRDM), a data model underpinning the national data dictionary used for national data holdings.

- Canada has a long history with health data exchange or interoperability. Methods of data exchange vary and interoperability standards include Health Level Seven version 2 messages, Health Level Seven version 3 messages, Health Level Seven Clinical Document Architecture, Health Level Seven Fast Healthcare Interoperability Resources (FHIR) and Integrating the Healthcare Enterprise.
- Canada invests heavily in collaborating with, and are well represented on, industry and standards development organisations.
- Canada collaborates extensively with various stakeholders including clinicians, vendors and subject matter experts to drive forward the eHealth agenda.

Chapter 5 New Zealand

5.1 Introduction

New Zealand currently has a population of approximately 4.9 million. It is a parliamentary democracy, an independent country and a constitutional monarchy. Health and disability services in New Zealand are delivered by a complex network of public and private organisations and people. The Minister of Health, with the cabinet and government, develops policies and provides leadership for the health and disability sector. In terms of public healthcare delivery, there are 20 district health boards (aligned to four regions) that take the lead for planning, procuring, and delivering healthcare services to their populations.[74,92]

New Zealand has invested significant effort in the area of electronic health. The government's electronic health goal is universal electronic access to a core set of patients' personal health information. Given that the district health boards are autonomous, there is a strong tendency for local services to take precedence over national projects. New Zealand's progress on interoperability is well renowned, with messaging standards allowing different care providers to communicate with each other.[93]

In 2017, New Zealand developed a Vision for Health Technology to guide how technology can ensure better health for all New Zealanders and commenced development of an updated national Digital Health Strategy to replace the 2010 National Health IT Plan.

The Digital Health Strategy envisions a 'digital health ecosystem that creates the conditions that support delivery of the Vision for Health Technology and government priorities'. [94,95]Interoperability is identified as a key enabler. The Digital Health Strategy is currently in the advanced stages of development. New Zealand has recently developed an interoperability roadmap (see section 5.4 below).[93]

5.2 Key organisations

There are a number of key organisations and boards with varying responsibilities in relation to health information (collection, use and sharing) in New Zealand. Those of most relevance to this review include the:

- Ministry of Health operates and manages the information technology (IT) network infrastructure that underpins national data collections and systems used in service delivery.
- District health boards (DHBs) – there are 20 district health boards (DHBs) in New Zealand, and each DHB is governed by a board of up to 11 members.

The board sets the overall strategic direction for the DHB and monitors performance.

- Health Benefits Limited is a ministerial owned, national shared services organisation and it assists in preventing duplicate reporting of clinical data by utilising the same contract across the country.
- National Health Information Technology Board is a sub-committee of the National Health Board and is the governing body for health information standards in New Zealand and has led the development of New Zealand's current electronic health record policy. The role of the board is to provide strategic leadership on health information systems. The National Health Information Technology Board developed a five-year IT plan for 2015 to 2019. Four priorities were identified for IT investment in 2014 and beyond: electronic medication management, national clinical solutions, regional information platforms, and community-based integrated care initiatives.
- The Health Information Standards Organisation is a committee responsible for the development, promotion and provision of support for health information standards that are fit for purpose across the health sector in New Zealand. Its work involves maintaining relationships with international and national organisations involved in standards development. Its governance includes a Health Information Standards Committee, with eight members including the chair. It has a terms of reference and is accountable to the Chief Technology and Digital Services Officer within the Ministry of Health.[96] The Health Information Standards Organisation is supported by the Architecture and Standards Team that sits within the Data and Digital Directorate.[97]

5.3 National data collections and a national data dictionary in New Zealand

New Zealand is a country with a centralised structure in place for health and social care data collections. Stipulated in different pieces of legislation is the Ministry's obligation to collect data. It has responsibility for the collection and dissemination of all health-related information in the country. The Ministry of Health collects data from different parts of the health sector (mostly from routine administrative systems) through the utilisation of health services, or the mandatory reporting national collections, and from national population health surveys.

The Ministry of Health manages national data collections of health and disability information, with the information group holding operational responsibility for these. On the Ministry of Health website (www.health.govt.nz), information specific to the individual collection is provided alongside each data collection. For example, information presented on the cancer registry includes purpose, commencement, availability and technical details on identity reporting, ethnicity, geographical coding, coding systems, data limitations and data quality measures. There is a secure network between the Ministry of Health and the district health boards for the

transfer of data and all national collections data is stored in the Ministry's data warehouse.(92)

5.3.1 Governance of national data collections

The Ministry of Health signs an operational policy framework (OPF) with the 20 district health boards each year. The operational policy framework (OPF) sets out the business rules, policy and guideline principles that outline the operating functions of district health boards and the responsibilities of the Ministry of Health in relation to national health information management and reporting requirements.

5.3.2 National data dictionary

Up to late 2013, New Zealand was utilising METeOR, Australia's repository for national metadata standards for health. This system was advantageous in that it managed a community of experts who could debate and agree definitions. However, the use of METeOR in the New Zealand context presented challenges when reporting, in part due to its complex structure and frequent queries around coding. The New Zealand interoperability roadmap states that they will 'build an online data dictionary and terminology service and publish our national code sets online' by January 2021.

5.4 eHealth developments in New Zealand

There are a number of eHealth initiatives in use in New Zealand, including:

5.4.1 National health identifier

In the mid-1970s, New Zealand began the move towards the digitisation of the New Zealand health sector with the introduction of a national health identifier for all people treated in New Zealand. This identifier was widely used in electronic clinical systems from the 1990s and is now one of the foundational enablers (along with the health provider identifier) for associating care events to a specific individual.(74)

5.4.2 Shared care record

New Zealand's shared care record is known as the shared electronic health record. It is a regional shared care record and contains information on medical conditions, allergies, recalls, immunisations, recent test results and prescription medication. Each region has appointed a governance group to ensure the project is implemented and evolves appropriately in each region.(98)

5.4.3 New Zealand electronic prescription service (ePrescribing)

The New Zealand electronic prescription service (NZePS) provides a secure messaging channel for prescribing and dispensing systems to exchange prescription

information electronically. It enables a prescription to be generated by the prescriber, transmitted to the NZePS health information exchange broker, and downloaded electronically at a community pharmacy. Data captured for the prescription service is not generally used for secondary purposes.[99]

5.5 Interoperability

The Ministry of Health has moved away from the idea of building a single electronic health record towards developing a National Health Information Platform that will enable data about a single patient to be shared. The Ministry will focus on joining up data to provide information about a patient via the National Health Information Platform. Interoperability is core to the new platform, which will have the ability to assemble a virtual electronic record on an 'as required' basis from multiple trusted sources, and provide access to data and services. The view is to integrate current data sources, accelerating the use of Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), Fast Healthcare Interoperability Resources (FHIR) and other standards. A business case has been developed but has not yet been approved. The Ministry of Health is planning a phased approach to implementation and aims to avoid 'lock in' to a single technology solution.

In most parts of New Zealand, the lack of interoperability makes it difficult to create joined-up services around the patient. Regional clinical data repositories for, electronic referral, electronic order, transfer of care and shared care solutions have been built to different standards around the country and cannot interoperate in most cases.[74] As mentioned in 6.3, typically data that are sent to the Ministry of Health for operational performance is exchanged using file transfer technologies. Electronic data exchange between primary care and secondary care and secondary care to primary care is increasing, especially with respect to referrals and discharge letters and documents, and diagnostic results.

The majority of data exchange between New Zealand's health provider organisations is transmitted over New Zealand's private health network known as Connected Health (established in 2009). Connected Health is currently undergoing an architecture and standards review to support a network-agnostic approach to the safe sharing of health information.

Interoperability is a key part of the Ministry's digital health strategic framework. New Zealand has recently published an interoperability roadmap (2020) which will 'accelerate a shift to a fully interoperable digital health ecosystem'. [95]The roadmap has four interwoven themes: connecting and identifying, using the same languages, unblocking access to data and enabling joined-up services. Standards are crucial to realising the vision of the roadmap. An overview of the standards is outlined in section 5.5.1.[95]

5.5.1 Standards

The interoperability and data exchange standards in use across New Zealand include:

- Health Level Seven v2.x messages, Fast Healthcare Interoperability Resources (FHIR)
- Health Level Seven Clinical Document Architecture documents (in a few cases only)
- terminologies and classifications: Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT).

Health Information Standards Organisation (HISO) has also endorsed the following standards for use across the health and disability sectors, which support the national IT plan:

- health and disability sector ethnicity data protocols
- ISO/IEC 11179, information technology — metadata registries.

The exchange of data for clinical referrals, orders, discharges, prescribing and dispensing, results management primarily use the Health Level Seven version 2.x messaging standard with small pockets using Health Level Seven Clinical Document Architecture (for example, ePrescriptions and patient data transfer between general practice) for document exchange. The Health Information Standards Organisation (HISO) intends to update its statement of endorsement of the Health Level Seven standards to reflect the growing importance of Fast Healthcare Interoperability Resource (FHIR) and its commitment to it. As one of the first steps, HISO accepted the following recommendation from Health Level Seven New Zealand on adoption of the Health Level Seven FHIR for the International Patient Summary Implementation Guide.[74]

5.5.2 Clinical Terminologies and Classifications

The Ministry of Health works across healthcare in New Zealand to improve health outcomes. The Ministry of Health leads New Zealand's health and disability system, and has overall responsibility for the management and development of that system.[100] It is responsible for clinical classifications and terminologies, including ICD10-AM, the Australian Coding Standards, the Australian Classification of Health Interventions, SNOMED CT NZ and the New Zealand Universal List of Medicines.

5.5.3 Ministry of Health

The Ministry of Health is responsibility for clinical classifications and terminologies that include ICD10-AM, the Australian Coding Standards, the Australian Classification of Health Interventions, SNOMED CT NZ and the New Zealand Universal List of Medicines.

5.5.4 Classifications

New Zealand uses ICD10-AM, the Australian Coding Standards and the Australian Classification of Health Interventions with modifications. The Australian Government gave permission for the classifications to be used for coding purposes in the New Zealand hospitals. The Ministry of Health developed and defined the *New Zealand Coding Convention*[101] and engaged with relevant stakeholders in this process. The *New Zealand Coding Convention*[101] sets out the additional requirements that had to be implemented by clinical coders in New Zealand. All coding requirements required to be adhered to were set out in the *New Zealand Clinical coding practice*,[102] including the National Minimum Dataset[103] reporting requirements and classifications.

The classification team is responsible for all activities in relation to ICD-10. In particular, it is responsible for ensuring that New Zealand works with Australia and international colleagues on classifications. This work involves the implementation of new editions of ICD-10AM in New Zealand and focuses on the quality of clinical coding including education.

5.5.5 SNOMED CT NZ

New Zealand was one of the founding members of SNOMED International. SNOMED CT NZ edition was endorsed as the information standard in New Zealand for the disability and health sector.[104] The NZ edition refers to the SNOMED extension used in New Zealand. The Ministry of Health is a member of SNOMED International, and hosts the National Release Centre. It is responsible for the deployment and operation of SNOMED CT, as well as promoting its use throughout New Zealand. Its objectives are to support implementers by the adoption of SNOMED CT in New Zealand.

The Health Information Standards Organisation hosted an expert group entitled 'SNOMED implementation working group' within the Ministry of Health. It met quarterly on a face-to-face basis and then worked virtually for the remainder of the time. In 2018, it became the SNOMED Adoption Accelerator NZ.[105] Its role includes 'innovation, motivation and communication'[105] in relation to SNOMED CT NZ edition. The membership is described as 'fluid' and takes into consideration the current work underway in New Zealand, ensuring the relevant skills and expertise are available

and learning is shared. There are between six and 12 projects being implemented at any one time, and the group's objectives are to apply the use of its thinking on SNOMED CT by being involved in projects that have the highest impact and lowest associated costs.(105)

The National Release Centre has formal governance processes in place for the development of new concepts, the promotion of a new concept from a member, or synonym. All requests in relations to SNOMED CT are submitted to the National Release Centre, which has established a formal process to deal with these requests. All the processes are set out in *Guidelines for SNOMED CT Content Request*(106) and are submitted in the *SNOMED CT Content Request Service Submission Form.*(107)

5.5.6 Universal List of Medicines

In 2011, the New Zealand Universal List of Medicines commenced operation. The Ministry of Health is responsible for its operations. It is the main naming and coding database for information on medications used in the healthcare sector.(108) This includes being the standard source used for most of the software in pharmacy and medicine for information on medications. The database integrates information on medication and uses a 'common medicines language' that is part of the New Zealand Medicines Terminology. It is used for prescribing, dispensing and administration. All the medicinal products are listed according the SNOMED CT standards and was built upon New Zealand's medicines terminology. This includes generic and trade names of medications.

5.6 Information architecture

An information architecture was developed in New Zealand to enable interoperability to support a shared care approach to delivering healthcare to a patient. One of the key building blocks proposed was a common shared content model, using the ASTM Continuity of Care Record (CCR) as the basis for describing core health information.

Several high-level principles underpin the information architecture in order to guide its development, the most relevant to this best practice review being investment in information and using a single content model for information exchange. These two principles are outlined below:

- Invest in Information — represent health data for exchange as detailed clinical models that can be represented in different ways independently of any particular information model (structure) and derived directly from business requirements with clinical input. These models may be represented in different ways for different audiences.

- Use a single content model — information for exchange will be defined and represented in a single consistent way at the information model level. Where possible, it will align with national and international standards.

CCR is a logical information model and will be discussed in further detail in section 5.7.2 below.

5.7 Information modelling

The adoption of published data standards is seen as fundamental to New Zealand's ability to collect and link clinical datasets. New Zealand plans to develop a set of data requirements for core personal health information, starting with immunisations, medications, allergies and adverse reactions. Using the Joint Initiative Council Patient Summary Standards Set as a reference point, specifications will be published in a user-friendly, technology-neutral format.(109)

A priority for New Zealand is to focus on the patient summary and it intends to follow the information model that the Joint Initiative Council use for a patient summary which is based on the ISO/IEC 11179 Metadata Registry (MDR) standard — an international ISO standard for representing metadata for organising data in a metadata registry. The Health Information Standards Organisation (HISO) advocates the need for a high level technology independent model. The Health Level Seven Fast Healthcare Interoperability Resources (FHIR) International Patient Summary Implementation Guide is recommended for the exchange of core personal health information and also as a starting point or building block for health systems. This recommendation is likely to be upgraded to a full endorsement when the implementation guide reaches normative status.

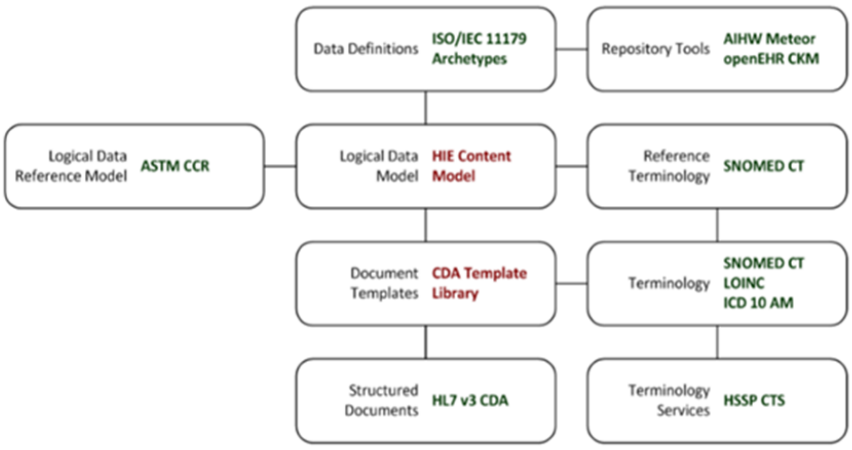
The Health Level Seven FHIR International Patient Summary Implementation Guide and related specifications will be used as the starting point for the national health information platform to set standards for medicines, allergies and adverse reactions, health conditions, immunisations, procedures, medical devices, diagnostics, vital signs, functional status, care plans, advance directives and risk factors.

5.7.1 Content model

This section presents the content model architecture building block, the common shared content model designed to achieve semantic interoperability in information exchange. The building block comprises architectural principles and requirements, organised under the headings: semantic interoperability, content model, data definitions, detailed clinical models, archetypes and terminology. Clinical information needs to be exchanged in a format that complies with the content model. The purpose of the content model is to enable semantic interoperability by providing fit-for-purpose, agreed and communicated data definitions. The content model is based

on the American Society for Testing and Materials, (ASTM) Continuity of Care Record (CCR) specification[28] and the vision was to adapt the model as data requirements in specialty areas were established and documented. The data definitions of the content model will be formulated according to the ISO11179 metadata standard with detailed clinical models expressed as ISO13606 archetypes that extend the model into specialty areas.

Figure 8 Content model for the ASTM Continuity of Care Record (CCR)



5.7.2 Clinical information models

The development of the content model was to follow the detailed clinical model (DCM) approach. The detailed clinical model approach is about creating reusable specifications of information requirements in a clinical domain to save time and effort in developing the content model. Detailed clinical models define maximal datasets, that isthey include all possible data elements that may be mandatory, optional or inapplicable depending on the application or context to promote the reuse and effectiveness of the detailed clinical model.

New Zealand promoted the use of archetypes as a way of describing structured health information in a way that can easily be understood and maintained. Archetypes represent the detailed clinical model in graphical form. The use of archetypes is another means (in addition to ISO/IEC 11179) of expressing detailed clinical models to make up the content model. However, in its recent interoperability roadmap, HISO outlined its position on the use of 'openEHR and detailed clinical models' stating they are:

> 'welcome in the environment, but they will not be delivered by national programmes nor positioned as Health Information Standards Organisation (HISO) standards. Previously, under our now-withdrawn reference architecture for

interoperability, openEHR had a level of endorsement, but FHIR is now more prominent and this is where our efforts will go.'[95]

5.7.3 Health Level Seven Fast Healthcare Interoperability Resources (FHIR)

Health Level Seven New Zealand has a national committee on Fast Healthcare Interoperability Resources (FHIR). Vendors in New Zealand say they are fully FHIR compatible. New Zealand has endorsed the FHIR standard for exchanging health data and will invest in tools that allow projects to build, maintain and publish nationally agreed FHIR projects. They will support a model-driven approach to software development by publishing technology-neutral dataset specifications that can be fed into the FHIR resource design process. Projects such as the National Immunisation Register (NIR) replacement and the national health information platform will develop the FHIR profiles and implementation guides they need and publish them via a national registry.

5.8 Governance

The IT Health Board is the governing body for health information standards in New Zealand. The Health Information Standards Organisation (HISO) is the expert advisory group for standards of the IT Board, working to advise on, identify, scope, develop and endorse standards. Outlined in the recent interoperability roadmap, New Zealand plans to establish co-stewardship of data standards with medical colleges, national clinical networks and other stakeholders, such as the Royal College of Pathologists of Australia, National Pathology and Laboratory Round Table, New Zealand Microbiology Network and Emergency Department IT (EDIT), following the approach of the Professional Records Standards Body in England. New Zealand also plans to establish an interoperability maturity model and regularly assess functionality, standards, adoption level and governance.[95]

5.9 Key learnings

- There is a high level of maturity regarding eHealth systems in New Zealand with a national health identifier, a shared care record and electronic prescribing in place.
- New Zealand has robust governance structures in place to ensure successful interoperability of health information systems including

information modelling. An IT Health Board is the governing body for health information standards, with a long-standing expert advisory group called Health Information Standards Organisation (HISO). New Zealand also plans to regularly assess functionality, standards, adoption levels and governance of eHealth.

- National data collections, managed by the Ministry of Health, are well advanced with good governance practices in place. Governance of national data collections in New Zealand is guaranteed by the Ministry of Health who signs an operational policy framework (OPF) with the 20 district health boards each year.
- New Zealand continues to make advancements regarding their national data collections, using METeOR — Australia's repository for national metadata standards for health based on the ISO/IEC 11179 data model. The recent New Zealand Interoperability roadmap states that it will 'build an online data dictionary and terminology service and publish our national code sets online' by January 2021.
- Consideration has been given to an information architecture to enable interoperability to support a shared care approach to delivering healthcare to a patient. One of the key building blocks proposed in its reference architecture is a common shared content model for structuring health information.
- Similar to Australia, New Zealand has historically used detailed clinical models and openEHR archetypes to define and implement its clinical information models, but are now putting efforts into Health Level Seven Fast Healthcare Interoperability Resources (FHIR) which has its own information models available for use.
- Stakeholder engagement is key and as outlined in the recently published interoperability roadmap, New Zealand plans to establish co-stewardship of data standards with medical colleges, national clinical networks and other stakeholders, following the approach of the UK's Professional Records Standards Body.

Chapter 6 England

6.1 England

It is estimated that the population of England is over 55 million. Healthcare in England is mainly provided by England's public health service, the National Health Service (NHS).(110)

6.2 Key organisations

There are a number of key organisations with varying responsibilities in relation to electronic health and national data collections in England. These include:

- NHS Digital, founded in 2013, has responsibility for standardising, collecting and publishing data and information from across the health and social care system in England. NHS Digital's mission is to 'harness the power of information and technology to improve health and care'.(111) The governance of NHS Digital is overseen by the Board, an executive team and a clinical leadership team.(112) The NHS Digital Board reports to the Department of Health and Social Care. The Board comprises of non-executive directors and directors, and is accountable to the Secretary of State for Health, the public and parliament. NHS Digital is organised into seven directorates: Strategy Policy and Governance, Product Development, Data Services, Platforms and Infrastructure, Live Services, Corporate Services and Assurance and Risk Management.(113)
- Public Health England is an executive agency of the Department of Health and Social Care and a distinct organisation with operational autonomy. It collects and publishes statistics on public health topics, including health protection and health improvement. It is responsible for researching, collecting and analysing data to improve understanding of public health challenges and to come up with answers to public health problems.
- NHSX brings teams from the Department of Health and Social Care, NHS England and NHS Improvement together into one unit to drive digital transformation and lead policy, implementation and change. NHSX aims to deliver the 'the future of healthcare: our vision for digital, data and technology in health and care' building on the NHS Long Term Plan.(114)

6.2.1 National data collections

NHS England has power under the Health and Social Care Act 2012 to direct NHS Digital to collect information from health organisations. This is done to establish collections of information that can be used to monitor how well the NHS is performing and the quality of care provided. As the data is held centrally, it can be linked to provide information that would not otherwise be possible.

NHS Digital manages routine national data collections, helps healthcare professionals submit data and offers guidance for using data collection systems. The Burden Advice and Assessment Service makes sure every collection is efficient and needed, reducing the burden on health and social care wherever possible. NHS Digital manage a number of data collections covering many aspects of health and social care collected from a wide variety of NHS trusts, local authorities, and independent-sector organisations.

National data sets collect information from care records, systems and organisations on specific areas of healthcare. This is used to inform policy and monitor and improve care. The Department of Health and NHS England collect data so they can learn about specific areas of policy interest and measure the progress of policy initiatives. NHS Digital works with these partners and groups of health and social care professionals, patients and IT system suppliers to design and develop national data collections. NHS Digital provides updates on approved, past and proposed data collections.(115)

6.2.2 The NHS Data Model and Dictionary

The NHS Data Model and Dictionary gives a reference point for assured information standards, to support healthcare activities in the NHS in England. The NHS Data Model and Dictionary has been developed for everyone who is actively involved in the collection of data and the management of information in the NHS and supports the development and maintenance of NHS information standards. The NHS Data Model and Dictionary Service uses the 'Big Data Institute Oxford University' who provide the 'Mauro Data Mapper tooling'[8] and expertise to publish the NHS Data Model and Dictionary.(116)

6.2.3 How the NHS Data Model and Dictionary is published

The tools used to maintain and publish the NHS Data Model and Dictionary are described below. It uses a data model that has evolved and been refined since 2005. A project is underway to migrate to the 'Mauro Data Mapper (Mauro)' using a three phase approach.

- Phase one includes data migration from the existing platform to Mauro and publishing a web-accessible data model and dictionary designed to work with modern browsers and on modern devices, whether widescreen desktop computers, smaller tablets or mobile phones.

[8] Mauro is a free, open source metadata catalogue. The Mauro Data Mapper (also known as the Oxford Metadata Catalogue) is used to develop and maintain linked, versioned descriptions of data standards, datasets, and questionnaires. These descriptions capture essential structure and context together with a detailed account of each variable, comprising: name, natural language definition, data type, and multiplicity.

- Phase two will see the NHS Data Model and Dictionary Service move to maintain the data model and dictionary using Mauro. In parallel, NHS Digital is extending its use of Mauro to understand other datasets it receives with the aim of developing a common map of its data sets. This extension includes data specifications for the delivery of care including the UK core Health Level Seven FHIR resources. During phase two, NHS Digital intends to make the full NHS Data Model available for computer consumption with an Application Programming Interface and also make all of the codes and descriptions used in the NHS Data Model and Dictionary available as FHIR resources through a FHIR terminology server.
- The final phase is to start moving to a single logical model with data collected for secondary uses, such as performance management, commissioning or research, demonstrating their links to the data recorded in care records. This phase will see the NHS Data Model uplifted from Version 3, introduced in 2005, to Version 4. Underpinning the final version of the model will be the ISO concept model of the health and care business, ISO 13940:2015 - A system of concepts to support the continuity of care.[116]

6.3 eHealth developments in England

There are a number of eHealth initiatives in use in England, including:

- National health identifier (NHS number)
- Summary care records
- Local Health and Care Record Exemplars
- Electronic prescription service (ePrescribing)
- NHS electronic referral service.

6.3.1 National health identifier

An NHS number is given to every citizen registered with the NHS in England. It is given to the patient when they register with a general practitioner (GP) practice, and it allows for healthcare staff to match details to health records. There is no option to opt-out of this but if a person requests the national data opt-out, their personal data will not be used for purposes beyond their individual care.

6.3.2 Summary care records

Summary care records (SCRs) are an electronic record of important patient information created from GP medical records. Generally, access to SCR information means that care in other settings is safer, reducing the risk of prescribing errors. It also helps avoid delays to urgent care. At a minimum, the core SCR holds important information about:

- current medication

- allergies and details of any previous bad reactions to medicines
- the name, address, date of birth and NHS number of the patient.[117]

The summary care record is currently used for individual care only and not for secondary purposes beyond the care of the individual.

6.3.3 Local Health and Care Record Exemplar

A Local Health and Care Record Exemplar (LHCRE) is a regional collaboration across health, care and local authorities to develop shared health records for the people in the region. The Local Health and Care Record Exemplar was launched in 2018. Its aim is to design shared records for improving and coordinating individual care. The intention is that, regardless of where an individual is receiving care and support (at their GP, hospital, and community hospital or even at home), the health professionals looking after them can access the right information, at the right time. The primary focus of the Local Health and Care Record Exemplar is to create integrated healthcare records for individual care. However, NHS England's five regions are also considering how shared healthcare records could be used to support purposes beyond individual care, such as improving health and services through research and planning.

6.3.4 Electronic prescribing

The NHS Electronic Prescription Service (EPS) allows GPs and other prescribers to send prescriptions electronically to a dispenser (such as a pharmacy) of the patient's choice. Eventually EPS, or ePrescribing, will remove the need for most paper prescriptions. This makes the prescribing and dispensing process more efficient and convenient for patients and staff. EPS is now used in additional care settings, such as integrated urgent care. [118,119]

6.3.5 NHS electronic Referral Service

The NHS e-Referral Service combines electronic booking with a choice of place, date and time for first hospital or clinic appointments. It was fully rolled out in 2018. Patients can choose their initial hospital or clinic appointment, which they can then book online (a telephone service is also available) or in the GP surgery at the point of referral. All 150 acute hospital trusts and GP practices have made the move to sending and receiving all first outpatient referrals through the NHS e-Referral Service.

6.4 Interoperability

England takes a system-wide approach towards interoperability, focusing on the following areas:

- Working with services to identify their strategic business needs in relation to interoperability to inform development of required solutions.
- Development of priority use cases for interoperability to provide business justification for local investment and development of supporting systems and products nationally.
- Supporting local organisations with tools and guidance to enable them to develop effective solutions to interoperability problems.
- Developing standards to support the move from paper to electronic transfers of care for, for example, discharge from inpatient care, discharge from mental health, emergency department attendance and outpatient clinic letters.
- Developing standards to support the move to systems enabling access to patient information through open interfaces (CareConnect APIs).
- Commissioning NHS Digital in the delivery of interoperability standards.
- Work with INTEROPen in the adoption of interoperability. INTEROPen is an OPEN collaboration of individuals, industry, standards organisations and health and care providers, that have agreed to work together to accelerate the development of open standards for interoperability in the health and social care sector (See section 6.4.1 below).

6.4.1 Adoption of interoperability

The Chief Clinical Information Officer for healthcare in England has outlined seven priority areas:

- **NHS number/Citizen ID** – real-time access to the NHS number at the point of care across the service, ensuring that the NHS number is associated with care record elements e.g. lab tests. The Provider must ensure that, with effect from 1 April 2020, the service user's verified NHS number is available to all clinical staff when engaged in the provision of any service to that service user – this is stated in the 2019 and 202020 standard contract.
- **Medications** – all medication messages in the NHS to be interoperable and machine readable across the service.
- **Staff ID** – ensuring that there is a consistent way to identify and authenticate staff across the service.
- **Dates and scheduling** – a consistent set of interoperability standards for dates and scheduling information that enables a consistent approach to appointment booking across venues of care and the creation of historic and forward views of appointments.
- **Basic observations** – a consistent set of interoperability standards for the sharing of a core set of structured observations.
- **Basic pathology** – a consistent set of interoperability standards for the sharing of a core set of pathology tests.

- **Diagnostic coding** – implementation of SNOMED CT across the wider service. SNOMED CT must be utilised in place of read codes before 1 April 2018 across primary care settings. For secondary care, acute care, mental health, community systems, dentistry and other systems used in the direct management of care of an individual must use SNOMED CT as the clinical terminology before 1 April 2020.

6.4.2 NHS Standard Contract requirements

The NHS Standard Contract has required organisations to align their inpatient, emergency care, mental health discharges and outpatient letters to nationally published specifications. Providers must ensure that its major clinical information technology systems enable clinical data to be accessible to other providers of services to service users as structured information through open interfaces in accordance with Open API policy and guidance.

6.4.3 Health data exchange

Health data are being exchanged for numerous purposes across all care settings, including social care. The data are used for both individual care and secondary uses, including:

- patient identification – between organisations and in interactions with national services;
- transfers of care – national standards exist for acute, accident and emergency and mental health eDischarges and letters from outpatient clinics;
- record level transfers of information between care settings;
- imaging; and
- pathology.

The 'transfers of care' and 'record level transfers' have national specifications which include structures for the exchange of medications, allergies, diagnoses, procedures, immunisations, observations and encounters. A range of standards are currently in use:

- Health Level Seven version 2.x – extensive local use
- Health Level Seven version 3 – use for existing national components such as general practice, personal demographic service and so on
- Health Level Seven Fast Healthcare Interoperability Resources (FHIR)– for newer specifications
- Bespoke extensible markup language (XML) – use for several secondary uses collections

- Systematized Nomenclature Of Medicine Clinical Terms (SNOMED CT) – the primary clinical terminology
- Digital Imaging and Communications in Medicine (DICOM) – international imaging standard and
- Integrating the Health Enterprise – various Integrating the Health Enterprise (IHE) standards are deployed by local organisations and regional structures though there is no national implementation.

Health Level Seven Fast Healthcare Interoperability Resources (FHIR) is the strategic direction for future standards development. In England, NHS Digital is working on several FHIR projects, including collaboration with the Professional Record Standards Body and the INTEROpen vendor group to provide clinical validation of FHIR profiles for use in the NHS and social care. Other examples of FHIR-based projects in England include GP Connect and the Diagnostic Data Service. The GP Connect project allows general practice and other systems to work together opening up information and data held within GP Practice IT systems for use across health and social care. Additionally, NHS Digital has decided to replace the national primary care pathology report message with a FHIR messaging specification.[120,121]

6.5 Stakeholder engagement

Leading organisations and individuals have come together to create INTEROPen, an action group to accelerate the development of open standards for interoperability in the health and social care sector. INTEROPen is an OPEN collaboration of individuals, industry, standards organisations and health and care providers, who have agreed to work together to accelerate the development of open standards for interoperability in the health and social care sector. INTEROPen members have access to a collaboration platform, Ryver, where members share resources, announcements and work together on the design and application of technical interoperability standards. INTEROPen activities include educational events, co-production of CareConnect FHIR profiles and APIs, data validation, hackathons and well as the governance and adoption of standards into the service. Commercial interests are put to one side in the group's activities. INTEROPen is governed by a board of representatives that meets each month to discuss ideas and projects, develop the ambitions of the community and check that progress is in line with INTEROPen's vision, mission and values. INTEROPen board members represent interoperability stakeholders from across health and social care. The Board of Representatives includes representation from:

- NHS Digital
- Professional Record Standards Body
- Orion Health, cerner
- British Computer Society

- Integrating Health Enterprise
- Clinical Council Information Officer Network
- Health CIO Network
- North Yorkshire County Council
- openEHR
- Health Level Seven.

6.6 Clinical terminologies and classifications

NHS Digital is responsible for clinical classifications and terminologies including ICD-10, SNOMED CT, Read Codes and the NHS Dictionary of Medicines and Devices.

6.6.1 Classifications

The classifications used in England are ICD-10, OPCS-4 and the National Interim Clinical Imaging Procedure Code Set. NHS Digital is responsible for the maintenance and publication of all ICD Classifications and OPCS-4 Information Standards for the United Kingdom (UK). This includes the provision of support in implementing clinical classifications and derivative products. The NHS Digital Terminology and Classifications Delivery Service is responsible for setting national clinical coding standards and providing guidance in England for these classifications.[122] NHS Digital is responsible for the maintenance of all ICD classifications including ICD-10 used in the NHS, licenced by the WHO.[123] The Collaborating Centre for ICD-10 is situated within NHS Digital and is used to code diagnoses in the NHS.

6.6.2 OPCS Classification of Interventions and Procedures (OPCS-4)

The Office of Population Censuses and Surveys (OPCS) Classification of Interventions and Procedures (OPCS-4)[124] is a classifications of statistics and an information standard. It was developed by the NHS on behalf of the Department of Health. The NHS is responsible for its licensing and maintenance. It is used to classify the interventions and procedures carried out across the NHS. There is a mandatory requirement that OPCS-4 is used for all reported episodes of secondary care, as well as reimbursement for all NHS admitted patients. It is used to report requirements under the NHS Admitted Patient Care Commissioning Data Sets. Any requests for changes are made via the request portal.[124]

6.6.3 Terminologies

The main terminologies used in England are SNOMED CT,[125] the Dictionary of medicines and medical devices[126] and the National Interim Clinical Imaging Procedure.[127]

6.6.4 SNOMED CT UK

NHS Digital is responsible for SNOMED CT in the UK and is the national representative to SNOMED International. The National Release Centre for SNOMED CT is situated within NHS Digital[125] and is known as the United Kingdom Terminology Centre. NHS Digital is responsible for the management and distribution of SNOMED CT in England. Governance is provided externally by the United Kingdom Strategy Board for SNOMED CT in Scotland, Wales and Northern Ireland.[125] In England, releases are made every six months for SNOMED CT UK in both April and October. Any changes to SNOMED CT had to be made through the Request Submission Portal.[128] The move to the use of a single terminology nationally — SNOMED CT — in primary care was implemented by December 2019. The transfer to the use of SNOMED CT from read codes was carried out under the National GP Systems of Choice Framework.[9][129,130]

6.7 Governance

Led by the Secretary of State for Health, the Department of Health provides strategic leadership for healthcare in England, while the NHS England is responsible for the day-to-day delivery of health services across England. The digital health programme is being progressed through a portfolio of programme delivery aligned to the overall business strategy of the NHS. This strategic direction has been outlined in the NHS Five Year Forward View.[131] The NHS England is a national, single-payer health system with highly centralised governance and management. This allowed the adoption of a highly centralised approach to architecture, standards compliance and procurement process. Local organisations are responsible for the provision of electronic systems within hospitals and other care settings.

6.7.1 Digital Delivery Board

In April 2017, the Digital Delivery Board was established, bringing together the Department of Health, NHS Digital, NHS England. It is chaired by the Chief Clinical Information Officer from NHS England. It delivers the strategy for healthcare and is responsible for the implementation of the *Personalised Health and Care 2020.*[132] It has three subgroups:

- Enterprise Architecture Board
- Technology and Data Investment Board
- Data Coordination Board.[133]

[9] GP Systems of Choice Framework was a contract that supplied information technology systems to GP's and finished in 2018.

6.7.2 Data Coordination Board

In 2017, the Data Coordination Board took over the national governance of standards from the Standardisation Committee for Care Information.[134] The Data Coordination Board is a sub group of the Digital Delivery Board.[133] This resulted in a number of changes within NHS Digital. These changes consisted of a dedicated team with responsibility for the approval of new information standards, continuous assurance of standards and making required changes to existing ones. This included new processes for the submission of proposals and changes to standards. The Data Coordination Board meet on a monthly basis to review, approve data collections and provide assurance on information standards.[135]

An information standard is defined under legislation in the Health and Social Care Act 2012 as 'a document containing standards that relate to the processing of information'.[136] There is a data standards team in NHS Digital that works on 'international and national standards for categorising and recording information'.[137] The data diagnostic services team is responsible for improving the quality of information in the diagnostic services, including 'pathology, endoscopy, imaging, physiological measures and genomics'.[138]

There is a formal two stage process in place to make changes to information standards that are presented to the Data Coordination Board: an initial and final stage.[133] The initial stage involves an assessment report that provides an overview of the proposed changes relating to an existing or a new standard. This process involves receiving the approval to proceed to the assurance of Information Standards Collection and Extractions. The final stage involves an assessment report that summarises what assurance and appraisal has been completed against the Information Standard Collection and Extraction, with final approval from the Data Coordination Board requested. An assurance mark[139] is then provided to the successful organisation that owns the standard. A standard that is fit for purpose, receives an assurance certificate[139] which applies to that individual standard and not the organisation. Subject matter experts are involved throughout the process. The publication, entitled *Standards Assurance Guidance,*[133] sets out the assurance process required. All information regarding new standards or changes to existing ones were published on the activity page of the Data Coordination Board website.

6.7.3 Data Standards Assurance Service

The Data Standards Assurance Service is situated within NHS Digital. The service provided support to both the Data Coordination Board and the Data Coordination Sub Board. This support centres on the provision of assurance, as well as appraisal of all proposals for 'Information Standards, Collections and Extractions', as required

under legislation as set out in the Health and Social Care Act 2012.[136,140] The Data Standards Assurance Service ensures that when an Information Standard Collection and Extraction is developed:

- All obligations under the Health & Social Care Act 2012 are met by the developer.
- Any burden on the system is acceptable in relation to benefits.
- The assured Information Standards Collection and Extractions are aligned and complied with existing published standards.
- Risks and impacts are considered, addressed and mitigated within the development of the Information Standards Collection and Extractions.
- The Information Standard Collection and Extractions could be implemented across the system.
- Any data required to flow across the system because of the Information Standard Collection and Extractions has a legal basis, addresses any information governance requirements and ensures that fair processing has been considered.[140]

The Data Coordination Board publishes the standards after the assurance process is completed.[140] All health and social care organisations, including adult social care services in England, are required to consider and use all information standards published as set out under legislation in the Health and Care Act 2012.[136]

6.8 Key learnings

- There are good governance structures in place to manage eHealth in England with well-defined organisational responsibilities and strategic direction for their digital health programme outlined in the National Health Service Five Year Forward View.
- There is a high level of maturity regarding eHealth systems in England with a national health identifier, summary care records, ePrescribing, electronic referral and Local Health and Care Record Exemplars in place.
- Significant investment has been awarded to their national data collections and responsibility rests with NHS Digital. They continue to advance their infrastructure for national data collections. An NHS Data Model and Dictionary exists that has evolved and been refined since 2005. There is a

three-stage plan in place to move the Data Model and Dictionary to a single logical model with data collected for secondary uses, demonstrating their links to the data recorded in care records.

- England has a long history with health data exchange and a range of standards are currently in use including Health Level Seven version2.x (extensive local use), Health Level Seven version 3 and Health Level Seven Fast Healthcare Interoperability Resources (FHIR) – for newer specifications. Bespoke XML is used for several secondary uses collections.
- Health Level Seven FHIR – is the strategic direction for future standards development in England.
- Stakeholder engagement is key to defining and developing clinical information models. NHS Digital is working on several FHIR projects, including collaboration with the Professional Record Standards Body (PRSB) and the INTEROpen vendor group to provide clinical validation of FHIR profiles for use in the NHS and social care.

Chapter 7 Denmark

7.1 Introduction

Denmark has a population of 5.7 million people. The Danish healthcare system is universal and based on the principles of free and equal access to healthcare for all citizens. The system is heavily financed by public funds, experiences little inequality and has notably high levels of user satisfaction.[141] The majority of all health and social services are financed by general taxes. Approximately 80% of healthcare expenditure is publicly financed with the remaining 20% financed primarily through patient co-payments.

Denmark is widely considered a global leader in eHealth. Several studies and reports have highlighted Denmark's high levels of eHealth use in hospitals, primary care practices, and patient population. The European Union has identified Denmark as one of the countries who has the potential to provide leadership and inspiration for other countries in eHealth implementation and adoption.

7.2 Health and social care system in Denmark

The health and social care system operates across three political and administrative levels: the national level (state), the regional level (five regions) and the local level (98 municipalities).

- The state, through the Ministry of Health holds responsibility for overall regulatory and supervisory functions providing legislation and the overall framework for health and elderly care.
- The five regions — Capital Region of Denmark, Region Zealand, Region of Southern Denmark, Central Denmark Region and North Denmark Region — are governed by regional councils, elected every four years. The regions are responsible for hospital care, including emergency care, psychiatry, and health services provided by general practitioners and specialists in private practice.
- The 98 municipalities and local administrative bodies are responsible for a number of health and social services. Local health and elderly care services include disease prevention and health promotion, rehabilitation outside hospital, home nursing, school health services, child dental treatment, child nursing, physiotherapy, alcohol and drug abuse treatment, homecare services, nursing homes, and other services for elderly people.

7.3 Key organisations

In Denmark, the governance of eHealth is the responsibility of several organisations. The organisations that play a key role in relation to information modelling for the collection, use and sharing of health information systems in Denmark.

7.3.1 The Ministry of Health

At the governmental level, the Ministry of Health consists of a department as well as a number of boards and authorities that work to ensure a well-functioning and efficient health system. Organisations that are relevant to eHealth, include the:

- Danish Health Data Authority
- MedCom (project organisations that run cross sectorial IT projects and solutions)
- Sundhed.dk (national eHealth portal).

7.3.2 The Danish Health Data Authority

The Danish Health Data Authority was established in 2015 and co-ordinates efforts required for cross-sector exchange of health data through goal setting, strategies, and agreements and promotes a coherent data and IT architecture within the healthcare system information technology (IT) architecture. Setting national standards for digitisation and enhancing data security, the Danish Health Data Authority supports the general digitisation process. It is responsible for a large number of databases, registers, services and infrastructure that involve data on diagnosis, treatment (including drug prescriptions) and population health.[142,143] The information in the registers comes from hospitals and GPs who record every time a person has been in contact with the Danish healthcare system. There are a number of registries such as the National Children's Database, the National Patient Registry, the Product Statistics Register and the Death Register. The Danish Health Data Authority publishes a large number of reports based on data from the health registers. [143]

7.3.3 Sundhed.dk (Health Portal)

Sundhed.dk is the national eHealth portal in Denmark. Sundhed.dk was initiated in 2001 by the Association of County Councils in Denmark, the Ministry of Interior and Health. Since its launch in 2003, sundhed.dk provides several functionalities such as quality assured health information, access to some parts of medical records and medication, and an overview of the Danish healthcare system. It is unique in that it brings the entire sector together online and provides an accessible digital forum. All citizens can use this platform, thus enabling patients to both communicate with healthcare professionals and also gain clear overview of a full set of up-to-date relevant information. Likewise, doctors, nurses, consultants and care providers have

secure and controlled access to data regarding the patients they are treating. It creates links between existing data sources, exposes datasets to new user groups, and facilitates communication between healthcare providers and citizens.(141)

7.3.4 MedCom

MedCom was established in 1994 as a publicly-funded, non-profit co-operation. MedCom facilitates the communication between authorities, organisations and private firms linked to the Danish healthcare sector. MedCom is financed and owned by the Ministry of Health, Danish Regions and Local Government Denmark. It has four main activities:

- Cross-sector dissemination — providing support and information for healthcare professionals, particularly through telemedicine solutions and exchange of data such as exchange.
- Standard, test and certification — MedCom's standards are the foundation for exchanges of relevant data between the different parts of the healthcare sector. MedCom documents, tests and certifies IT vendors' implementation as well as offering support, consultancy and training courses.
- System management — MedCom is responsible for a number of public IT solutions.
- Application, participation and project-management in relation to EU projects are part of MedCom's international activities. In addition, MedCom promotes Danish health IT and international standardisation initiatives.(144)

7.4 eHealth development in Denmark

Denmark is an international leader in digital health. Increasing use of common IT standards facilitates electronic communication among all healthcare providers – including hospitals, general practitioners, specialists, laboratories, local authorities, and home care services.(97) For example, the current situation in Denmark is noteworthy with:

- All general practitioners maintaining electronic health records (EHRs). Information from these electronic health records is added to national health registries.
- ePrescribing — 99% of all prescriptions are sent electronically to the pharmacies.
- eReferral — 97% of all referrals to hospitals are made electronically.
- Shared Medication Record — contains up-to-date information on every citizen in Denmark and is shared across all local systems in healthcare.

- Patient portal — Sundhed.dk allows citizens to access their own medical data from national health registers, electronic health records and medication data.(144)

7.4.1 The Danish eHealth strategy

Denmark has had national eHealth strategies since the late 1990s. Initially, these strategies focused on digitalisation of the healthcare sector. A lot of the focus in the first years was on development and implementation of electronic health records (EHRs) in the hospitals. Nevertheless, electronic medical records (EMRs) were introduced in primary care (GP and private practitioner) already by the mid-1990. By 2000, the whole Danish healthcare system was digitalised, thus all healthcare professionals are using electronic documentation systems, capable of communicating. Over the years, the national strategies were built upon some basic policies:

- A multi-vendor environment – Each healthcare organisation is free to choose and implement eHealth application of its own choice.
- All healthcare organisations must adhere to and implement commonly agreed interfaces, standards, terminologies and classifications in order to maintain both technical and semantic interoperability.
- Profiles and exchange interfaces for electronic communication in the healthcare sector are developed in a consensus process.
- National standardisation is the responsibility of the Ministry of Health. The ministry can delegate the operational responsibilities.(145)

The current national strategy, *A Coherent and Trustworthy Health Network for All – Digital health strategy 2018-2022*, was launched to advance sustainable development of the Danish healthcare system. (146)The strategy includes 27 initiatives within five main areas: engaging citizens as active partners; ensuring timely knowledge exchange; developing the field of population health and prevention; providing excellent data security to win trust; and implementing a flexible digital healthcare infrastructure. Besides increasing the efficacy of healthcare delivery, the information recorded and collected during digitised workflows feeds on a daily basis into Danish population-based data sources.

7.4.2 Strategy for use of healthcare data

Denmark is a world leader in unique healthcare registers and infrastructure for linking data across registers and databases. Biobanks and registers provide detailed information on the entire population that can be used for research and improvement of healthcare services. A reform to improve the visibility of results has been initiated and marks a commitment to a national long-term strategy for better use of healthcare data and for creating greater transparency of health outcomes and

results. As part of the visibility of results reform, a Health Data Programme was established in 2014 to run over a four-year period. The vision of the Health Data Programme is to create 'better healthcare through better use of data', and four separate programme tracks have been defined to support this vision:

- New data model and user interface. Developing a modernised data model and easy accessible user interface that gives better access to relevant healthcare data for healthcare professionals, researchers, administrators and citizens.
- Modernised infrastructure. Developing the IT infrastructure for national health data management at the National Health Data Authority, including a modernised data platform.
- Better data quality. Enhancing quality of the healthcare data by establishing a new national governance model for monitoring data quality in order to support higher validity and reliability of healthcare data.
- Better cross-sectorial cooperation. A new governance model for health data management to support cross-sectorial cooperation.

7.4.3 eHealth developments

There are a number of eHealth initiatives in use in Denmark, including:

- National health identifiers
- Electronic health records
- Sundhed.dk web portal
- Shared medication record
- Electronic referrals.

7.4.4 National health identifiers

Denmark has been very much at the forefront of a data-driven approach to health information. A central driver in this has been the widespread use of a unique personal identifier that has been adopted across multiple sectors to aid integrating digital processes since it was introduced in the late 1960s. Unique patient identifiers are used across health and social care and civil administration databases.[141]

7.4.5 Electronic health records (EHRs)

In 2014, the first version of the national health record was launched to provide clinicians with an overview of a patient's data stored across all the regions and within the various health sectors. The national health record can be used to access clinical notes, laboratory data, and medication, diagnostic and imaging data and includes the recent hospital visits, recent medication orders, allergies and the contact details of their primary care physician.[147] All GPs keep electronic health records (EHRs), and 98% exchange records electronically. Every time patients in Denmark attend the doctor, the pharmacy, the emergency room or have any other

contact with the healthcare system, the healthcare professional records information about the event in the patient's EHR. This data is added to national registries, such as the National Patient Register which is managed by the Danish Health Data Authority.[143]

7.4.6 Sundhed.dk web portal

The web portal Sundhed.dk allows citizens to access their own medical data such as EHRs at hospitals, medication data and laboratory results. These data can also be accessed by the patient's GP. Patients can also access general information on health, diseases and patient rights through this online portal.[143]

7.4.7 Shared medication record

The shared medication record has been under development since 2007 when the Danish Health Data Authority set out to establish a nationwide shared medication record, containing up-to-date information on prescription medicine on every citizen in Denmark and shared across all local systems in the healthcare sector. Almost all (99%) of all prescriptions are sent electronically to pharmacies.[143] The shared medical record was developed with the shared involvement of many different stakeholders, including the Ministry of Health, the Danish Health Authority and local governments, a private vendor, together with the Danish Health Data Authority. The shared medication record was available in all public hospitals (except one) by mid-2014. However, regional use of the Shared Medication Record differs significantly. The region of Southern Denmark (80%) and region Zealand (76%) were among the top users in comparison with North Denmark (69%), the capital region of Denmark (62%) and Central Denmark region (31%).[147]

The shared medication record is a vital database at the Danish Health Data Authority, storing data on all Danish citizens' current medication plans, electronic prescriptions and medicine purchases. The Shared Medication Record has processed over 500 million prescriptions since it launched in 2009. the shared medication record is used today by almost all healthcare professionals in Denmark across the sectors. In total, about 40 different systems have integrated with the Shared Medication Record.[142]

7.4.8 Electronic referrals

Electronic referrals (eReferrals) were among the first MedCom standards which were tested in Denmark in 1995 to 1996. An analysis of communication flows between GPs and the rest of the healthcare sector showed that electronic referrals was one of the most frequently used messages along with discharge summaries, laboratory requests and results, radiology requests and results, prescriptions and messages to and from the municipality. The 'eReferral Hotel' was established through which all

electronic referrals from the general practitioners are exchanged. This means that the patient is free to select any (relevant) specialist they want once a referral is made, instead of making that decision together with the GP. Since almost all referrals are electronic and used by all GPs in the Danish healthcare sector today, there is no official strategy and vision for the eReferral service. The region's finance the hotel as agreed in the collective agreement between the government and the regions. All GPs use eReferrals. This is also established in an agreement between the GPs and the government.(144)

7.5 Interoperability

Important prerequisites to enable semantic interoperability (data exchange) and standardisation have been implemented almost 100% in Denmark, including:

- Unique Person ID — life-long and multi-purpose (since 1968) – contains all with a permanent residence in Denmark
- National registration of hospital contacts (since 1976)
- Legal authorisation registry — all healthcare professionals are listed with public access
- Health provider registry (since 2006) — all healthcare providers are listed
- National security services — with a national service platform and national PKI infrastructure
- National health insurance — a single payer tax financed healthcare service
- National IT strategies — covering all sectors
- National classifications and terminology
- National catalogue for exchange interfaces and standards.(144)

Health Level Seven Clinical Document Architecture (CDA) profiles are used for sharing information across sectors, regions and municipalities. The *Program for Patients with Complex pathways* develops Health Level Seven Clinical Document Architecture (CDA) profiles for appointment, shared personal data card and treatment plans and activities. Health Level Seven Clinical Document Architecture (CDA) is recommended for document-based collaboration on document sharing platforms that is IHE XDS.

The Danish catalogue of standards contains more than 200 standards in use. Some of the international standards in use are:

- Clinical Documents: Health level seven (Clinical Document Architecture)
- Infrastructure: IHE (XDS)
- Messaging: EDI-FACT.(104)

7.5.1 Clinical terminologies and classifications

The Danish Health and Medicines Authority has a national license for SNOMED CT. This license covers the use of SNOMED CT in the country, and disseminating the SNOMED CT terminology in Denmark is the responsibility of the National Release Centre. The National Release Centre is responsible for both international and national tasks, such asinternational obligations as well as communicating, administering, servicing and developing SNOMED CT across the country.

Some of the responsibilities of National Release Centre include:

- Translating new SNOMED CT concepts into Danish
- Creating SNOMED CT concepts in Danish
- Contact those who are interested in CNOMED CT
- Administrating access and use of SNOMED CT
- Disseminating and support of SNOMED CT nationally and internationally
- Communicating with other National Release Centres
- Contacting directly to International Health Terminology Standards Development Organisation

7.6 Information modelling

The Danish Agency for Digitization within the Ministry of Finance was established in 2011 to be in charge of the government's digitisation policies. The Danish Agency for Digitization is responsible for the implementation of the government's digital strategy for the public sector. By sharing infrastructure components and by using open standards, the Danish Agency for Digitization aims to ensure that digitisation in the public sector does not develop the same components more than once, but reuse shared components where possible, by using open standards to avoid provider lock-in with proprietary solutions.

National models are being used based on international standards for modelling. The Danish Agency for Digitization has made shared model rules aimed at promoting modelling that can ensure that the data collected and handled in public organisations can be easily understood and recycled across the public sector. The rules are based on a number of principles of good modelling and a modelling method that promotes business clarification and recyclability. The modelling method involves separating the modelling work in such a way that independent business areas are modelled independently. Health Level Seven Version 3 Reference Information Model has been accepted as a requirement for modelling health in Denmark.[148]

7.7 Involvement in international initiatives related to standards

The Danish Health Data Authority is represented in different international standardisation organisations and workgroups. The Danish Health Data Authority participates, among others, in:

- Nordic Council of Ministers — eHealth Network, eHAction
- Health Level Seven Denmark
- ISO working groups in health informatics (TC215, CEN/TC251)
- Personal Connected Health Alliance (PCHA)
- Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)
- World Health Organization (WHO)
- The Nordic Medico-Statistical Committee.

Denmark uses meetings where software developers meet to connect to each other's systems and request and read data. 4S is a shared ecosystem consisting of a board, a coordinator, a software group and a number of professional forums. It supports knowledge sharing and provides open tools, platforms, tutorials and guides available. 4S works closely with users like regions, municipalities and companies for use and further development.(148)

Health Level Seven Denmark (HL7-Denmark) is the Danish affiliate of Health Level Seven International managed by the Danish Standards Foundation which participates in work on developing international Halth Level Seven standards in health informatics. HL7-Denmark focuses on profiling and application of standards at national level. HL7-Denmark is working towards a shared definition of rules and frameworks, and how standards can be used most appropriately. The main actors involved in HL7-Denmark are regions, MedCom, vendors, GS1, Alexandra Instituttet, Aalborg University and Danish Health Data Authority.

7.8 Governance

There is a governance model in Denmark to support parties that are involved to prioritisation and implementation of the work with reference architectures and standards. A national board was established to advise the Minister of Health of responsibility for overall IT architecture and setting standards. An advisory committee has been established to assess and select standards and assess architecture in the field of health. The advisory committee on standards and architecture (RUSA) consists of 10 members who have different business approaches in the field. It helps ensure that the Danish Health Data Authority's assessments and options are dealt with from political, business and professional perspectives. The committee meets four to six times annually – organised so that the committee can process recommendations to be presented for the national board of eHealth.

The digitalisation strategy supports the performance of all tasks under the Health Act, covering all authorities as well as public and private actors involved in the carrying out of the tasks. This includes actors ranging from hospitals to GPs, from fertility clinics to nursing homes and hospices, and from pharmacies to auxiliary centres. The strategy focuses on the citizen as an individual and patient, and thus the individual's ability to influence their own health and actively contribute to prevention and treatment.(148)

The architectural governance of standards is related to standardisation processes and governance described in the Danish model for governance, where the National Board of eHealth has main responsibility.

MedCom is the main provider for maintaining international standards for use in Denmark. It leads the working groups where all parties are invited to join in this effort, which involves regions, municipalities, GP organisations, vendors, the Danish Health Data Authority and the GTS institutes that offer knowledge, technology and consultancy (GTS – Advanced Technology Group is a network consisting of independent Danish research and technology organisations).

7.9 Key learnings

- There are robust governance structures in place in Denmark with clear responsibilities for eHealth, IT architecture and for setting eHealth standards with a national board and an advisory committee.
- Denmark has been very much at the forefront of a data-driven approach to health information, with ational health identifiers, electronic health records, web portal, shared medication record and electronic referrals all in place.
- The Danish health system has a first-rate information infrastructure, including an electronic medical record system that has a large degree of interoperability across settings and is used across the whole healthcare system.
- Denmark has a long history with developing health registers and over 200 registers have been established, resulting in very rich datasets from many decades.
- Modelling information is based on models defined for use across the entire public service in Denmark. The Danish Agency for Digitization has made shared model rules aimed at promoting modelling that can ensure that the

data collected and handled in public organisations can be easily understood and recycled across the public sector.

- Denmark invest heavily in collaborating with and are well represented on industry and standards development organisations.
- Denmark engages with key stakeholders through a shared ecosystem called 4S consisting of a board, a coordinator, a software group and a number of professional forums. They organise meetings where software developers including vendors meet to test systems. 4s also works closely with users such as regions, municipalities and companies for use and further development of eHealth developments.

Chapter 8 Summary of current situation in Ireland

This chapter will summarise the current Irish electronic health landscape and progress made regarding health information modelling. An overview of the governance structure and the key organisations responsible for eHealth are outlined, including the key strategies and implementation plans that are available to drive eHealth in Ireland. An outline of the key eHealth programmes and their maturity is also described.

There is a focus throughout the chapter on initiatives that support the development of clinical information models. As mentioned previously, there are numerous standards that are needed to develop and implement clinical information models. A national standards catalogue has been published in Ireland to support the secure interoperable exchange of health information and includes standards that apply to clinical information modelling. An information or architectural framework called the *Integrated services framework* was developed and an architectural principles document has been published to support the need for true interoperability. Defining information in a consistent way so it can be shared between systems effectively is one of the key principles.

Examples of ongoing projects that are of interest are described further in this chapter, including: the national data dictionary — given this review examines models that support the national data dictionaries for national data collections—, the European Union Directive of Cross Border Exchange of Health Data which uses the Health Level Seven Clinical Document Architecture and underlying Health Level Seven reference information model to exchange clinical documents and the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) work ongoing in Ireland, which is a clinical terminology referenced in other countries as the coding used for binding to clinical information models.

8.1 Governance

The Department of Health has overall responsibility for leadership and policy decision-making in the Irish health sector, while the Health Service Executive (HSE) is tasked with implementing and providing Ireland's public health services in hospitals and communities across the country.[149] The Department of Health published its *eHealth strategy for Ireland* in 2013 and set up an eHealth Ireland committee.[150]

The HSE has established the Office of the Chief Information Officer (OCIO),[151] which has responsibility for implementing Ireland's eHealth Strategy. The OCIO is responsible for the delivery of technology to support healthcare across Ireland and has published the *Knowledge and Information Strategy* (2015)[152] in this regard detailed in section 8.1.1.

The Sláintecare Implementation Strategy[1] details clear plans to improve eHealth. There is a Research and Development and Health Analytics Division within the Department of Health to deal with information policy, while responsibility for eHealth and health information lies with the Sláintecare programme implementation office within the Department of Health.

8.1.1 Knowledge and Information Plan

The *Knowledge and Information Plan* (2015),[152] outlines the proposed national architecture for health information in Ireland. Both the National Data Dictionary, which defines the clinical and business terms across the healthcare enterprise, and the EU Cross-Border Directive 2011/24/EU which provides the infrastructure to exchange health data for electronic prescriptions and electronic patient summaries across European countries, were highlighted as key projects to drive the eHealth agenda forward. Both projects are described in more detail below.

In 2015, the HSE also identified a number of key national strategic electronic health programmes including the:

- Electronic Health Record (National Shared Care Record, Community, Acute and Integration capability)
- Individual Health Identifier
- PrimaryCare IT
- ePharmacy
- Maternal and Newborn Clinical Management System
- National Medical Laboratory Information System
- National Integrated Medical Imaging System.

8.2 Current eHealth Landscape

The Access to Information (A2I) programme,[153] positioned within eHealth Ireland, is tasked with the delivery of the technical infrastructure needed to enable the integration of health information across the health sector and to provide secure access to electronic health records (EHRs). It includes the development of key eHealth Strategy enablers such as the: individual health identifier (IHI),[154,155] which enables the identification of health service users and their health records; National Health Messaging Broker (HealthLink); and the national health mail (Healthmail), which is a secure, private, bounded email service for the exchange of patient identifiable clinical information.

Considerable progress has been made in relation to implementing the individual health identifier (IHI) and efforts are ongoing to operationalise the individual health identifier (IHI) programme into healthcare settings. Additionally, the implementation of the individual health identifier for organisations and professionals is in progress.

Access to Information (A2I) provide a web-based messaging service, via the National Health Messaging Broker, (HealthLink), which allows the secure transmission of clinical patient information between hospitals, healthcare agencies and general practitioners (GPs). The Health Level Seven version 2.x standards are the most commonly used standards in Ireland and continue to be supported for existing projects. Health Level Seven version 3 messaging is not currently used. The Health Level Seven Fast Healthcare Interoperability Resources (FHIR) standard is currently being used for the national individual health identifier programme, and a FHIR interface has been developed.

The national electronic referral programme in Ireland was first piloted in 2011 and has continued to grow. The aim was to deploy an electronic referral (eReferrals) solution that is accessible, transparent, measurable, robust and scalable to facilitate a GP to electronically refer a patient to a healthcare provider in secondary care. The HSE, in collaboration with HIQA and Irish College of General Practitioners, developed a standardised general eReferrals template. Healthlink developed the technical capability to implement the eReferrals solution. The national electronic referral programme has continued to evolve and GPs across the country can now refer patients into every acute hospital electronically.[156]

8.3 Health Service Executive Enterprise Architecture

The Enterprise Architecture and the Design Authority, within the HSE's Office of the Chief Information Officer (OCIO), is responsible for supporting the strategic development of technical architecture, technology and operational capabilities. The Design Authority defines standards, blueprints, and a test and assurance environment. The function is also responsible for data assurance including data security, information governance and semantic interoperability.[157]

8.3.1 Architecture principles

The Enterprise Architecture function published a document on architectural principles — *OoCIO Architecture Principles V2 (2018)*[158] — that reflect eHealth's strategic purpose, vision and values. There are 10 principles defined in the document. For the purpose of this review, the most relevant are in relation to 'common vocabulary and data definition' which describe how data should be 'defined consistently throughout the enterprise, and the definitions are understandable and available to all users', supporting the National Data Dictionary that will be used uniformly throughout the

healthcare enterprise. The principles also support the need for technical, syntactical and semantic interoperability.

8.3.2 Standards catalogue

The *HSE Design Authority ISF Programme ICT Asset Base Workstream 2.4 Standards Catalogue standards catalogue*[159] outlines the technical, data exchange and security standards needed to support the secure interoperable exchange of health information in Ireland. It provides guidance and direction for local and national HSE electronic health projects which can make informed decisions on using standards for particular use cases. It provides a practical, clear guide outlining the most suitable standards for the present and near future, and which follow European and international trends. The catalogue provides:

- an overview of each standard in order to allow the reader to understand how each standard works and why it is listed in this catalogue
- a brief description of the Standards Organisations and Standards Development Organisations (SDO) for background information
- and a formal procedure and associated policies to support the use and maintenance of this document.

8.3.3 National information and communications technology (ICT) Integrated Services Framework

The Enterprise Architecture function established the 'Information Services Framework' (ISF) project. The project is framed as an enabler for improving healthcare safety, quality and efficiency through a standards-based approach. It is an interoperability framework that defines a 'shared standards-based tool and language to describe the business and interoperability context for Ireland's electronic health systems'.[160]

The Integrated Services Framework aims to help to overcome data silos that exist within healthcare, and has been developed from a technical and a business perspective. It aligns with mandatory national and European standards. It was developed in collaboration with academia and other national agencies. It aims to ensure key systems can share data in a timely and organised fashion.

The framework is comprised of 12 work streams,of which work streams five to eight are about information architecture. The focus to date has been on the information architecture aspects of the Integrated Services Framework, most specifically the

- National data dictionary
- European Union Directive of Cross Border Exchange of Health Data
- Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT).

Each project is outlined in more detail in the following sections.

8.3.4 National data dictionary

A 'National Health and Social Care Data Dictionary' was established under the Enterprise Architecture function and was identified in the Knowledge and Information Plan of 2015, as being a core deliverable to provide '… consistency, governance and a standards based common language which will bridge the gap between medical, IT and Business worlds, serving as a foundational building block of the electronic health record (Electronic Health Record)'. [152] By standardising data definitions and promoting consistency of use, the national data dictionary enables comparable health information across all HSE-funded services, regardless of the systems or organisation from which the data was sourced.[161]

The national data dictionary is a reference point for all standardised healthcare terms that can be used when collecting data and for the purpose of organising data in a consistent way. It provides a list of key health service terms and concepts, including agreed definitions and protocols. Information regarding data elements is compiled, published and shared in the national data dictionary.

Where new projects are being introduced, the Office of the Chief Information Officer (OCIO) provides assistance in the creation of datasets and alignment with existing datasets, including a toolkit to support the standardisation of data. Additional terms, concepts and metrics are published in January and July each year, as agreed by the Dictionary Governance Board.

8.3.5 EU Directive of Cross Border Exchange of Health Data

The European Union (EU) Cross Border Directive 2011/24/EU relates to the introduction of cross-border care through the secure exchange of patient information between participating member states. The two use cases that were selected for implementation in EU member states are the exchange of electronic prescribing and patient summaries.

The main standard used to implement the secure exchange of the electronic prescribing and patient summaries is the Health Level Seven Clinical Document Architecture standard and Integrating the Health Enterprise profiles were also used.

Both ePrescribing and patient summaries are expected to be implemented in 22 European Union countries by 2021. The EU Open National Contact Point (Open NCP) initiative supports the development of the national infrastructures to exchange health data safely between EU member states. Ireland has committed to develop the infrastructure to enable transmitting health data to another member state.

The Open NCP framework relies on a core set of clinical codes, including SNOMED CT, which are referred to as the 'Master Value Catalogue'. This aligns with the adoption of SNOMED CT as the national clinical terminology needed for the meaningful sharing of data among member states.[162,163]

8.3.6 Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)

As outlined in Chapter 2, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) is a global terminology for use in clinical information systems. It was developed to improve the quality of clinical data in patient records in order to help improve the overall quality of care received by patients. Following recommendations from HIQA, the Irish Government has adopted SNOMED CT as a national terminology standard and has purchased a national licence for SNOMED CT.

The SNOMED CT National Release Centre of Ireland was established to meet Ireland's responsibilities to administer the national license for SNOMED CT, as outlined by SNOMED International.

The SNOMED CT National Release Centre has developed an Irish Edition of SNOMED CT, based on input from national stakeholder organisations and in line with guidance from SNOMED International. The Irish Edition is released biannually. The Irish National Release Centre has also produced a vendor specification for SNOMED CT, ratified and endorsed by the SNOMED CT Governance Board and by the SNOMED International Team. This specification has been approved by the Office of the Chief Information Officer, together with the Department of Health and the HSE Enterprise Architecture, for inclusion in all procurements.[32,164]

Regarding the national data dictionary, a dataset specification management process was a requirement of the SNOMED Governance Board, to ensure that all clinical datasets aligned with SNOMED CT.

8.4 Conclusion

Ireland has much to learn from the experience of other countries in the area of health information modelling. These lessons particularly relate to the governance arrangements that exist for health information systems — including national data collections and ehealth systems — in other jurisdictions, experiences with engaging and collaborating with key stakeholders, and implementing different types of information models and the standards they use to do so.

This best practice review identified that common themes emerged from reviewing the five jurisdictions, including: leadership, governance and management; maturity of ehealth services; information frameworks; interoperability; information modelling; governance of eHealth; stakeholder engagement; and collaboration with national

and international standards development organisations. All themes are important considerations for modelling health information.

While the health systems in the jurisdictions reviewed vary considerably and the approaches taken to information modelling also differed, a common thread has been the transition to using Health Level Seven Fast Healthcare Interoperability Resources (FHIR) resources as part of their information modelling approach. Australia, Canada, New Zealand and England have endorsed the use of Health Level Seven FHIR for future standards development and the development of new specifications for eHealth. All jurisdictions reviewed have strong leadership, governance and management in place, with clear organisational responsibility for managing health information systems. Feedback from the jurisdictions outlined that engagement with national stakeholders, and collaboration and involvement with international standards development organisations is an important role in health information modelling.

Having quality health information available when and where needed leads to quicker and more informed clinical decisions, and hence improvements in efficiency, patient safety and patient outcomes. In Ireland, health information is often of variable quality, where information is often duplicated and fragmented systems exist, contributing to cost inefficiencies and poor value for money. Implementing health information models can help to overcome some of these challenges.

Information models ensure that information is described consistently, and enables the safe exchange of information — ensuring that computers can share information that they can understand and interpret. Without implementing health information modelling, there is a risk that Ireland will continue to design its health information systems in isolation and miss the opportunity to develop health information system using a more national, strategic approach.

Appendix One Use Case: An information model for community-based ePrescribing in Ireland

This is an example use case for demonstration purposes to illustrate what a logical information model could look like and to give an example of a Health Level Seven FHIR resourse.

The following use case will illustrate how a clinical information model — such as a medication or a prescription item — can be defined once, and once agreed by all relevant stakeholders, it can be reused in different scenarios or use cases.

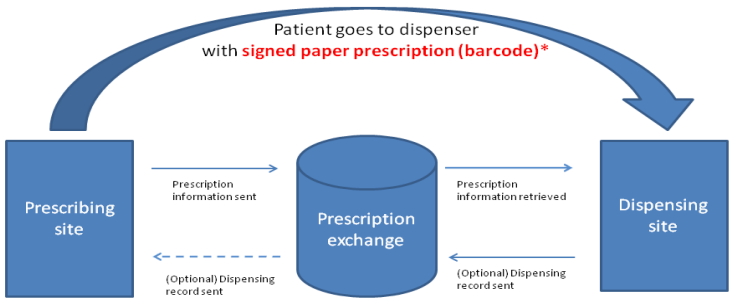
1. Aim

To design an information model for ePrescribing in community pharmacy to support the implementation of prescribing from patient to general practitioner (GP) to community pharmacy.

2. ePrescribing

ePrescribing can be described as a three-step approach (see Figure 1 below). First, at the time of prescribing medications for a patient, the prescriber's clinical information system generates the prescription in electronic format. Second, the electronic format of the prescription is transmitted to a prescriptions exchange or mailbox. Finally, when the patient presents in a pharmacy requesting their medication, the pharmacist retrieves the electronic prescription from the prescriptions exchange, the pharmacist dispenses medication (may be part or all of a prescription) and reports on the medicines given to the patient.

Figure 1 Three-step process for ePrescribing (HIQA, National Standard)



2.1 Process flow

Prescribers**,** such as GPs, send prescriptions electronically to a prescription exchange. A prescriber securely logs onto the clinical system, chooses medications or medical appliances for the patient, and applies an electronic signature to authorise an electronic prescription. An electronic prescription is transmitted to the prescriptions exchange. A paper prescription is printed where required.

A dispenser retrieves electronic prescriptions from the prescriptions exchange. This can also be done by scanning a barcode on a paper prescription. Prescription items are issued to the patient or patient's representative. A dispenser should record the status of each of the prescription items as one of the following: 'dispensed', 'not dispensed', 'owing' or 'partial'. If the dispensing process is complete, the dispenser sends a completed dispense notification to the message exchange.

To support the reimbursement claims process, dispensers can electronically submit reimbursement endorsement messages to the reimbursement agency for the dispensed electronic prescriptions so that the reimbursement agency can make a payment.

2.2 Community context

For the purposes of this example, community prescribing covers primary care prescribing and community pharmacy dispensing. The subject of care or patient is free to decide on what pharmacy they want their medicines dispensed from. Community prescribing also applies to where medicines are prescribed in outpatient settings or on discharge from hospital when the patient can fill the prescription at a pharmacy of their choice. It also applies in residential care settings, where the resident exercises their choice to manage their own prescription supply.

2.3 Assumptions

- The patient is not hospitalised.
- The prescriber is in most cases a GP, or a medical specialist in an outpatient clinic or in a private practice environment.
- The dispenser in most cases is a community pharmacist, who also will give any pharmaceutical advice.
- The medication administrator in most cases is the patient or someone from the family.

3. Methods

3.1 Identify entities, attributes and the relationships needed for community based ePrescribing based on the *National standard on information requirements for community-based ePresribing*.

3.2 Represent information requirements as a logical information model.

3.3 Map the model to a Health Level Seven FHIR resource to demonstrate a definition for an implementable clinical information model.

4. Clinical information model

4.1 Identification of entities, attributes and their relationships

Ten entities were identified and each entity, their attributes and relationships are outlined below.

Entity – Subject of care

Relationships: A subject of care has one to many encounters with a healthcare professional.

Attributes *Attributes taken from National Standard on ePrescribing except individual health identifier

1. Individual health identifier
2. Title
3. Forename
4. Surname
5. Address
6. Date of birth

Entity – Healthcare professional

Relationships: A healthcare professional has one to many encounters with a subject of care.

Attributes

1. Individual health identifier – Professional
2. Title
3. Forename
4. Surname
5. Address
6. Profession (e.g., physician, dentist, midwife, pharmacist, technician, nurse, etc.)
7. Specialty of the healthcare professional (e.g., general practitioner, cardiologist, gynaecologist, etc.)

8. Represented Organisation (primary care, pharmacy, hospital-OPD)

Entity – Healthcare provider

Relationships: A healthcare provider has one to many staff.

Attributes

1. Organisation Id(s)
2. Organisation name
3. Organisation contact details
4. Organisation department

Entity – Encounter

Relationships: A subject of care has one to many encounters with a healthcare provider

Attributes

1. Encounter ID
2. Healthcare institution information
3. Organisation department
4. Date of encounter
5. Time of encounter
6. Location

Entity – Medication

Relationships: A medication may cause an allergy, intolerance or contraindications. A medication relates to one prescription item.

Attributes

1. Brand name or generic name
2. Name of the manufacturer
3. National/regional drug code(s)
4. Active substance(s) denomination(s) (e.g., WHO ATC, International Non-proprietary Name – INN or other standard medicine terminology)
5. Codification of active substance(s)
6. Pharmaceutical form (tab, syrup, etc.)
7. Unit dosage/strength
8. Packaging, type of container, number of units
9. Economic information: price, reimbursement data, conditions, etc.
10. Prescribing rules (e.g., required specialty for the prescriber, limited time length, etc.)

11. Dispensing rules (e.g., to be delivered only at hospital, legal status)

Entity – Prescription

Relationships - A prescription is issued by one healthcare professional for one patient. A prescription may contain one or more prescription items (lines on a paper prescription). Each line relates to one medication or treatment.

Attributes

1. Prescription-id
2. Date written

Entity – Medication dispense

Relationships: A medication dispense relates to zero or one prescription items of one prescription. A medication dispense is issued by one pharmacy staff.

Attributes –

1. Dispense ID (Composite of prescription ID)
2. Date time of dispense event

Entity – Prescription item

Relationships: A prescription item relates to one prescription and represents one prescribed medication. It may be associated with one or more observations.

Attributes

1. Prescription Item ID
2. Treatment TimeLine
3. Beginning date of treatment
4. Length of treatment
5. End of treatment date (the date the treatment is due to end)
6. Number of refills
7. Reason for prescribing (e.g., diagnosis, prognosis, protocol, clinical assessment, etc.)
8. Intake pattern for the medication
9. Frequency and times of intake
10. Dosage
11. Route of administration
12. Medical instructions
13. Substitution allowed or not (can the pharmacist do a substitution of medication?)

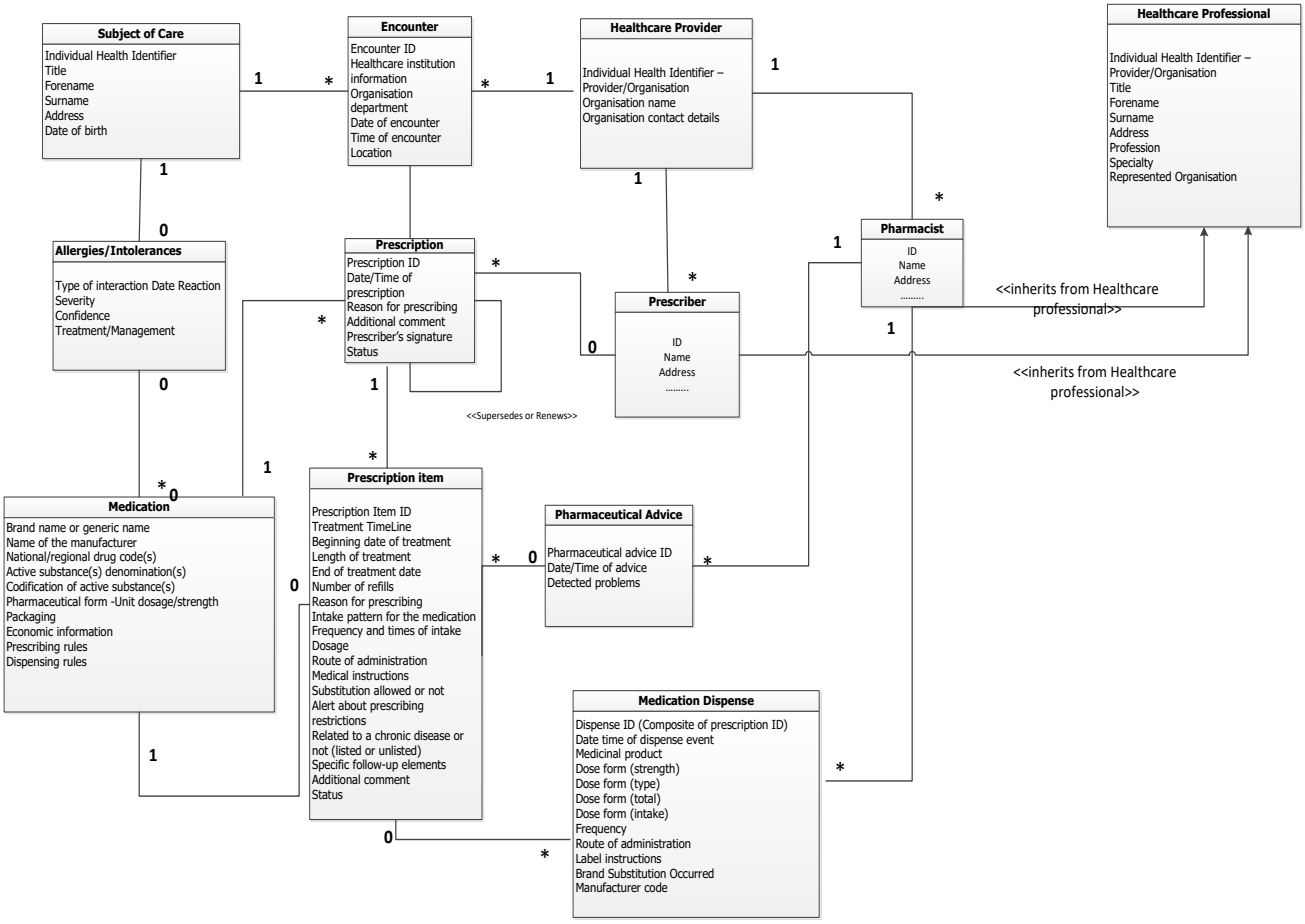
14. Alert about prescribing restrictions
15. Related to a chronic disease or not (listed or unlisted)
16. Specific follow-up elements
17. Additional comment (may be used by the prescriber to inform the pharmacist that he is aware of a potential allergies, intolerances)
18. Status

Entity – Allergies, intolerances, contraindications

Relationships: Allergies, intolerances, contraindications may be considered is a relationship between a patient and a medicine. A detected problem in a pharmaceutical advice may refer to an allergies, intolerances, and contraindications.

Attributes

1. Type of interaction
2. Date
3. Reaction
4. Severity
5. Confidence
6. Treatment/Management



The following use case will illustrate how a clinical information model, such as a medication or a prescription item, can be defined once, and once agreed by all relevant stakeholders, it can then be reused in different scenarios or use cases.

5.0 Mapping to international standards – Health Level Seven FHIR

This section will demonstrate the feasibility of mapping from the clinical information model for ePrescribing in community pharmacy to the Health Level Seven FHIR resource (logical information model). This is to demonstrate that a clinical information model is mapped to the technical standard, in this instance, Health Level Seven FHIR to enable interoperability between systems.

5.1 Health Level Seven FHIR Information model for a prescription

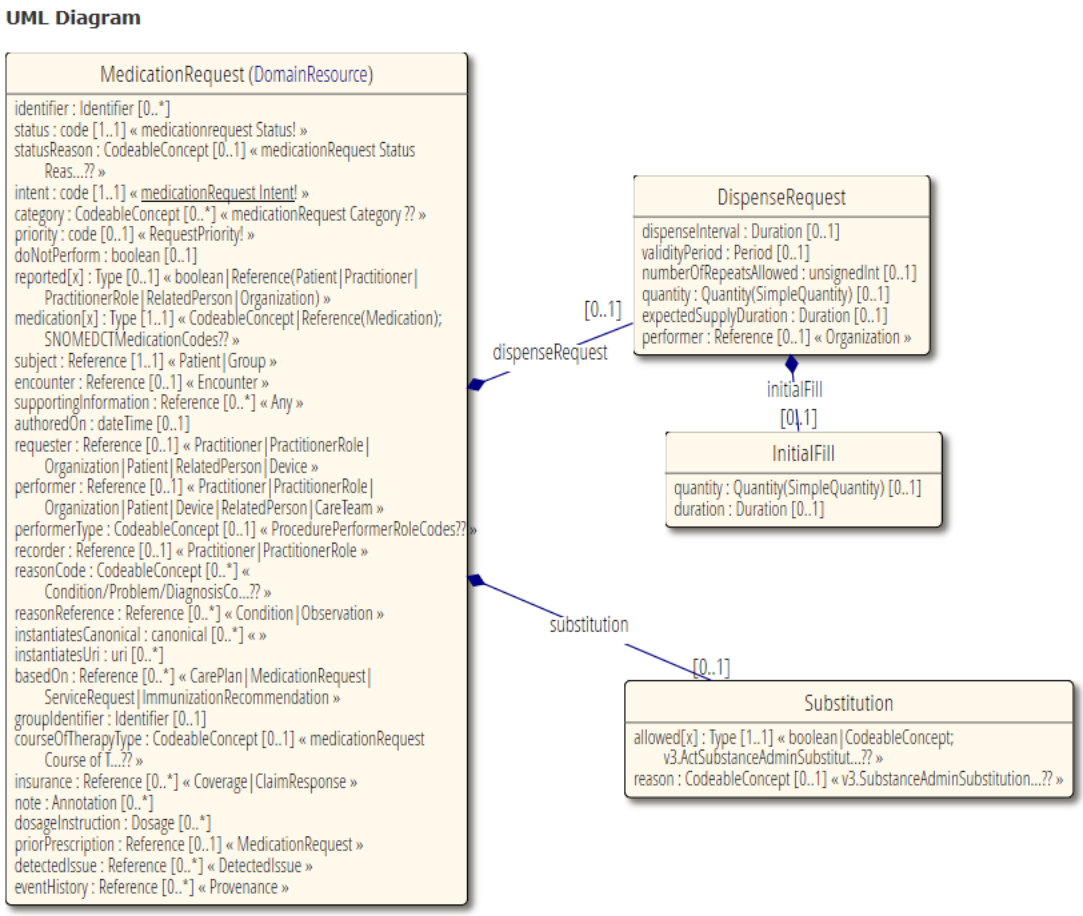
Health Level Seven FHIR supports a range of information models for medication a:

- medication statement
- medication request (order)
- provision/supply of a medication - a medication 'dispense'
- medication administration.

"The philosophy behind FHIR is to build a base set of resources that, either by themselves or when combined, satisfy the majority of common use cases. FHIR resources aim to define the information contents and structure for the core information set that is shared by most implementations. There is a built-in extension mechanism to cover the remaining content as needed." The UML diagram in Figure 2 below is provided in the Health Level Seven FHIR.

An order or request for both supply of the medication and the instructions for administration of the medication to a patient. The resource is called "MedicationRequest" rather than "MedicationPrescription" or "MedicationOrder" to generalize the use across inpatient and outpatient settings, including care plans, and so on, and to harmonise with workflow patterns.

Figure 2 FHIR resource for a MedicationRequest



MedicationRequest .DosageInstruction

CIM_Prescribing entity	FHIR Medication MedicationRequest Resource
1. Prescription Item ID	MedicationRequest.identifier
2. Treatment TimeLine	MedicationRequest .DosageInstruction
3. Beginning date of treatment	MedicationRequest.authoredOn
4. Length of treatment	MedicationRequest .DosageInstruction

5. End of treatment date (the date the treatment is due to end)	MedicationRequest .DosageInstruction
6. Number of refills	MedicationRequest.Dispense.NumberOfRepeatsAllowed
7. Reason for prescribing (e.g., diagnosis, prognosis, protocol, clinical assessment, etc.)	MedicationRequest.ReasonCode
8. Intake pattern for the medication	MedicationRequest.DosageInstruction
9. Frequency and times of intake	MedicationRequest.DosageInstruction
10. Dosage	MedicationRequest.DosageInstruction
11. Route of administration	MedicationRequest.DosageInstruction
12. Medical instructions	MedicationRequest.DosageInstruction
13. Substitution allowed or not (can the pharmacist do a substitution of medication?)	MedicationRequest.Dispense.Substitution.type
14. Alert about prescribing restrictions	MedicationRequest.note
15. Related to a chronic disease or not (listed or unlisted)	MedicationRequest.note
16. Specific follow-up elements	MedicationRequest.note
17. Additional comment (may be used by the prescriber to inform the pharmacist that he is aware of a potential allergies, intolerances)	MedicationRequest.note
18. Status	MedicationPrescription.status

5.2 Mapping from HIQA_ePrescribing Standard to HL7 FHIR Medication information model

CIM_HIQA_ePrescribing	HL7 FHIR Resource Medication Prescription
Date written	MedicationRequest.authoredOn
Medicinal product	MedicationRequest.medication
Dose form (strength)	MedicationRequest.Medication.ingredient.amount
Dose form (type)	MedicationRequest.Medication.ingredient.form
Dose form (total)	MedicationRequest.dispenseRequest.quantity
Dose form (intake)	MedicationRequest.dosageInstruction.dose
Frequency	MedicationRequest.dosageInstruction.timing
Duration	MedicationRequest.dosageInstruction.timing
Route of administration	MedicationRequest.dosageInstruction.route
Advice to pharmacist	MedicationRequest.supporting information
Substitution	MedicationRequest.substitution
Indications	MedicationRequest.reason
Repeats	MedicationRequest.DispenseRequest.numberOfRepeatsAllowed
Number of Repeats	MedicationRequest.DispenseRequest.numberOfRepeatsAllowed
Advice to patient	MedicationRequest.dosageInstruction.patientInstruction

5.3 Example - OpenEHR Information model for a prescription

CIM Prescribing	OpenEHR Medication Prescription
Medicinal product	Medication Order.Activities.Order.Medication item

Dose form (strength) Dose form (type)	Medication Order.Activities.Order.Preparation detail
Route of administration	Medication Order.Activities.Order.Route
-	Medication Order.Activities.Order.Body site
-	Medication Order.Activities.Order.Structured body site
-	Medication Order.Activities.Order.Administration method
-	Medication Order.Activities.Order.Parsable direction
Medical instructions	Medication Order.Activities.Order.Specific directions description
Indications	Medication Order.Activities.Order.Dosage justification
Frequency and times of intake	Medication Order.Activities.Order.Structured dose and timing direction
restrictions	Medication Order.Activities.Order.Medication safety.Exceptional safety override?
restrictions	Medication Order.Activities.Order.Medication safety.Saftey override.ovveriden safety advice
restrictions	Medication Order.Activities.Order.Medication safety.Saftey override.ovveriden reason
-	Medication Order.Activities.Order.Medication safety.Maximum dose.Maximum amount
-	Medication Order.Activities.Order.Medication safety.Maximum dose.Maximum amount unit
-	Medication Order.Activities.Order.Medication safety.Maximum dose.Allowed period
-	Medication Order.Activities.Order.Medication safety.Totall daily effective dose.Purpose
Dose form (intake)	Medication Order.Activities.Order.Medication safety.Totall daily effective dose.Total daily amount
-	Medication Order.Activities.Order.Medication safety.Totall daily effective dose.Total daily amount unit
Additional comment	Medication Order.Activities.Order.Additoianl instruction
Advice to patient	Medication Order.Activities.Order.Patient information
Specific follow-up elements	Medication Order.Activities.Order.Monitoring instruction
Reason for prescribing	Medication Order.Activities.Order.clinical indication
Reason for prescribing	Medication Order.Activities.Order.Therapeutic intent
Beginning date of treatment	Medication Order.Activities.Order.order details.order start date/time
End of treatment date	Medication Order.Activities.Order.order details.order stop date/time
-	Medication Order.Activities.Order.order details.order start criterion
-	Medication Order.Activities.Order.order details.order stop criterion
-	Medication Order.Activities.Order.order details.administrations completed
-	Medication Order.Activities.Order.order details.duration of order completed
-	Medication Order.Activities.Order.order details.order summary
Number of refills/Repeats/ number of repeats	Medication Order.Activities.Order.Authorization directions
Label instructions	Medication Order.Activities.Order.Dispense directions. Dispence instruction
Dose form(total)	Medication Order.Activities.Order.Dispense directions.Dispense amount
Substitution	Medication Order.Activities.Order.Dispense directions.subsitution direction

-	Medication Order.Activities.Order.Dispense directions.Non-subsitution reason
-	Medication Order.Activities.Order.Dispense directions.Priority
Date time of dispense event	Medication Order.Activities.Order.Dispense directions.Dispensing start date
-	Medication Order.Activities.Order.Dispense directions.dispensing expiry date
-	Medication Order.Activities.Order.Dispense directions.dispense details
Advice to pharmacist	Medication Order.Activities.Order.Additoianl details
Additional comment	Medication Order.Activities.Order.Comment

6. Support for other use cases - Re-usable use case components

The following use case demonstrate the aspects of the model that can be reused and support other use cases.

1. Use Case - Support patient administration in a patient portal.	**Entities that can be re-used to support medication compliance**
Facilitate a patient to record their compliance with taking their medication versus what medication was dispensed, hence improving patient safety. The information model will facilitate structuring the data in a patient portal (via an app) and could be fed back to the clinical information system	Patient (subject of care entity) Medication (Medication entity)
2. Use Case - Medication prescribing in outpatient settings	**Entities that can be re-used to support medication compliance**
Need a statement of the medications taken by a patient at a snapshot in time. Then undertake a reconciliation and review step; a list of medications could be presented for review collated from all authoritative sources in order to improve safety and efficiency.	Medication Statement from patient/carer (Define new entity) discontinued a drug or started a new over-the-counter remedy.
Use Case 3 – Reimbursement	**Entities that can be re-used to support medication compliance**
Payments for services provided in the community by Community Pharmacies are made by the PCERS. Claim data is processed and payments are made by the PCERS under certain Schemes/Payment	Patient (subject of care entity) Prescription information (prescription item entity) Pack information (medication entity) Dispensing information (Medication Dispense entity) Dispenser (Healthcare Professional entity) Reimbursement information (Medication entity)

Other use cases that could benefit from this approach include medication management in inpatient settings and residential settings, for example medication reconciliation on admission; prescribing, dispensing and administration during admission; support for the discharge planning process (medications changes); and modelling a drug reference file.

7. Summary

The diagram in Figure 1 illustrates a use case for ePrescribing in the community. It could be broken into key business processes such as prescribing, dispensing, re-imbursement. Some of the entities can be re-used in other clinical scenarios and use-cases as outlined in Table 2. For example, the prescribing or dispensing entities can be used in secondary care for administration of medication on a ward.

Appendix Two Glossary of terms

Attributes	An attributes are properties of an entity. For example, a 'Person' entity type has the 'Date of Birth' attribute.
Clinical terminologies	A structured collection of descriptive terms for use in clinical practice.
Data	Data are numbers, symbols, words, images, graphics that have yet to be organised or analysed.
Database	A collection of data that is organised so that its contents can easily be accessed, managed, and updated.
Dataset	Data is collected by the information collections is usually presented in tabular form.
Data dictionary	A descriptive list of names (also called representations or displays), definitions, and attributes of data elements to be collected in an information system or database. The purpose of the data dictionary is to standardise definitions and therefore have consistency in the collection of data.
Data quality	Data that are complete, valid, accurate, reliable, relevant, legible and available in a timely manner.
eHealth	The combined use of electronic communication and information technology in the healthcare sector. The use of ICT in health products, services and processes combined with organisational change in healthcare systems and new skills, in order to improve health of citizens, efficiency and productivity in healthcare delivery, and the economic and social value of health.
entity	An entity is something about which an organisation needs to keep data on and can be a single thing, person, place, or object.
General practitioner	A doctor who has completed a recognised training programme in general practice and provides personal and continuing care to individuals and to families in the community.
Governance	In healthcare, an integration of corporate and clinical governance; the systems, processes and behaviours by which services lead, direct and control their functions in

	order to achieve their objectives, including the quality and safety of services for service users.
Health information	Health information is defined as information, recorded in any form, which is created or communicated by an organisation or individual relating to the past, present or future, physical or mental health or social care of an individual or group of individuals (also referred to as a cohort). Health information also includes information relating to the management of the health and social care system.
Health Level Seven Clinical Document Architecture (CDA) Refined Message Information Models (R-MIMs)	Refined Message Information Models (R-MIMs) are used to model specific case scenarios within the Health Level Seven V3 standard.
Healthcare	Services received by individuals or communities to promote, maintain, monitor or restore health.
Information	Information is data that have been processed or analysed to produce something useful.
Information and communication technology (ICT)	The tools and resources used to communicate, create, disseminate, store, and manage information electronically.
Information governance	The arrangements that are in place to manage information to support national health and social care data collections' immediate and future regulatory, legal, risk, environmental and operational requirements.
Interoperability	The ability of health information systems to work together within and across organisational boundaries in order to advance the effective delivery of healthcare for individuals and communities.
Key performance indicator (KPI)	Specific and measurable elements of practice that can be used to assess quality and safety of care.
Metadata	Can be defined as 'data to explain data'. Metadata provides summary information in a structured way about the content of a resource such as a report, a book or a dataset.
Minimum dataset	A minimum dataset is the least agreed number of data elements collected for reporting purposes.
National health and social care data collections	National repositories of routinely collected health and social care data, including administrative sources, censuses, surveys,

	and national patient registries in the Republic of Ireland.
OpenEHR	A not-for-profit organisation, whose mission is to enable the use of ICT to effectively support healthcare and medical research through the creation of open specifications, open source software and tools.
Prescribing	Prescribing is the process of sending medical prescriptions from healthcare professionals – via a computerised system – to pharmacies. The goal of ePrescribing systems is to reduce errors due to manual prescribing and incorrect fulfilment and to speed up access for the patient to necessary prescriptions. In Ireland, there is a legal requirement in Ireland to produce a paper prescription for patients to present to their pharmacist, but legislation is being drafted to allow for eprescribing.
Relationships	Relationships are the connections between entities.

References

1. Irish Department of Health *Slaintecare Implementation Strategy* [Online]. Available from https://www.gov.ie/en/campaigns/slaintecare-implementation-strategy/. Accessed on: 5 September 2018.

2. Nowlan WA Rector AL, Kay S, Goble CA, Howkins TJ. . A framework for modelling the electronic medical record. *Methods Inf Med* 32(2). Accessed on:

3. Health Information and Quality Authority (HIQA) *Overview of Healthcare Interoperability Standards* [Online]. Available from www.hiqa.ie. Accessed on:
4. A. Moreno-Conde, T. Austin, J. Moreno-Conde, C. L. Parra-Calderon, D. Kalra. Evaluation of clinical information modeling tools. *J Am Med Inform Assoc*. 2016; 23(6):[1127-35 pp.]. Accessed on:

5. Australian Digital Health Agency. Interoperability Framework v2.0. 2007.

6. Australian Digital Health Agency *Australian National Digital Health Strategy 2018-2022* [Online]. Available from https://www.digitalhealth.gov.au/australias-national-digital-health-strategy. Accessed on: 13 Sep 2017.

7. Australian Digital Health Agency. Interoperability Framework v2.0 2007. Available from: https://developer.digitalhealth.gov.au/specifications/ehealth-foundations/ep-1144-2007. Accessed on: 28/10/2020.

8. Benson T. *Training Material on Principles of Healthcare Interoperability HL7 and SNOMED*. 2009. Available from: http://www.abies.co.uk/. Accessed.

9. Healthcare Information and Management Systems Society. *HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organisations*. 2010. Available from: http://www.himss.org. Accessed on: 6/29/2012.

10. Department of Health and Children *Health Act 2007* [Online]. Available from http://www.oireachtas.ie/documents/bills28/acts/2007/a2307.pdf. Accessed on:
11. empirica GmbH on behalf of the European Commission. *ICT standards in the health sector: current situation and prospects Final Report Version 3.0*. 2008. Available from: http://ec.europa.eu/enterprise/archives/e-business-watch/studies/special_topics/2007/documents/Special-study_01-2008_ICT_health_standards.pdf. Accessed on: 3/12/2011.

12. International Standards Organisation. Metadata Registry, ISO/IEC 11179 2015. Available from: https://www.iso.org/standard/68766.html. Accessed on:

13. International Organisation for Standardisation. ISO/TS 13972:2015(en) Health informatics — Detailed clinical models, characteristics and processes 2015. Available from: https://www.iso.org/obp/ui/#iso:std:iso:ts:13972:ed-1:v1:en. Accessed on: 29/10/20.

14. International Organisation for Standardisation. ISO 13606-1:2019Health informatics — Electronic health record communication — Part 1: Reference model 2019. Available from: https://www.iso.org/standard/67868.htm. Accessed on: 29/10/2020.

15. National Information Standards Organization (NISO). *Understanding Metadata* NISO Press; 2001.

16. Clinical Information Modeling Initiative Work Group. *Clinical Informatics-Modeling Terms, Tools and Their iEHR Use*. 2012. Available from: https://wiki.hl7.org/Clinical_Information_Modeling_Initiative_Work_GroupClinical Accessed on: 08/01/2020.

17. Goussen et al. Detailed clinical models: a review *Healthcare informatics research*. 2010; 16(4):[201-14 pp.]. Accessed on:

18. European Patient Smart Open Services *D1.2.4 Evaluation results* [Online]. Available from http://www.epsos.eu/uploads/tx_epsosfileshare/D1.2.4_Evaluation_results_v1.0.pdf. Accessed on: 22 Dec 2017.

19. OpenEHR Foundation. *OpenEHR*. 2013. Available from: http://www.openehr.org/what_is_openehr. Accessed on: 2/1/2013.

20. Stroetmann et al. *European Commision, Semantic Health Report, Semantic Interoperability for Better Health and Safer Healthcare, Research and Deployment Roadmap for Europe*. 2009. Available from: http://ec.europa.eu/information_society/activities/health/docs/publications/2009/2009semantic-health-report.pdf. Accessed on: 7/2/2012.

21. openEHR. *openEHR Primer.* 2012.

22. Health Level Seven (HL7). *About Health Level Seven (HL7) International.* 2012.

23. Health Level Seven (HL7) *HL7 Version 2 Product Suite* [Online]. Available from http://www.hl7.org/implement/standards/product_brief.cfm?product_id=185. Accessed on:
24. Health Level Seven (HL7) *HL7 Version 3 Product Suite* [Online]. Available from https://www.hl7.org/implement/standards/product_brief.cfm?product_id=186. Accessed on:
25. Health Level Seven (HL7) *HL7 v3 RIM: Is it really that intimidating?* [Online]. Available from http://www.hl7standards.com/blog/2011/05/31/hl7-v3-rim-is-it-really-that-intimidating/. Accessed on:
26. Health Level Seven (HL7) *CDA® Release 2* [Online]. Available from http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7. Accessed on:
27. Health Level Seven (HL7). *HL7 Implementation Guide for CDA Release 2: Care record Summary Discharge Summary*. 2013. Available from: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=233. Accessed on: 2/27/2013.

28. Health Level Seven (HL7) *HL7/ASTM Implementation Guide for CDA® R2 -Continuity of Care Document (CCD®) Release 1* [Online]. Available from http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6. Accessed on:
29. Health Level Seven (HL7) *Fast Healthcare Interoperability Resources* [Online]. Available from http://hl7.org/fhir/index.html. Accessed on:
30. Integrating the Healthcare Enterprise. *About Integrating the Healthcare Enterprise*. 2013. Available from: http://www.ihe.net/. Accessed on: 2/1/2013.

31. A. Moreno-Conde, D. Moner, W. D. Cruz, M. R. Santos, J. A. Maldonado, M. Robles, et al. Clinical information modeling processes for semantic interoperability of electronic

health records: systematic review and inductive analysis. *J Am Med Inform Assoc*. 2015; 22(4):[925-34 pp.]. Accessed on:

32. SNOMED International *SNOMED CT: National Release Centre Guide* [Online]. Available from https://confluence.ihtsdotools.org/pages/viewpage.action?pageId=26837051. Accessed on: Apr 10th, 2017.

33. SNOMED International *SNOMED CT International Edition (Beta) January 2017* [Online]. Available from https://confluence.ihtsdotools.org/display/RMT/2016/12/07/January+2017+SNOMED+CT+International+Edition+Beta+release+available+to+IHTSDO+Members. Accessed on: Apr 10th, 2017.

34. SNOMED International *SNOMED CT Benefits* [Online]. Available from http://www.snomed.org/snomed-ct/why-should-i-get-snomed-ct. Accessed on: Apr 7th, 2017.

35. SNOMED International *SNOMED CT Starter Guide* [Online]. Available from https://confluence.ihtsdotools.org/display/DOCSTART. Accessed on: Apr 6th, 2017.

36. International Health Terminology Standards Development Organisation *Articles of Association of the International Health Terminology Standards Development Organisation* [Online]. Available from http://www.snomed.org/SNOMED/media/SNOMED/documents/IHTSDO-Articles-(English-company-limited-by-guarantee)-V2-3-(4823-6849-7819-2).pdf. Accessed on: 25 May 2020.

37. SNOMED International *What is a National Release Centre?* [Online]. Available from https://confluence.ihtsdotools.org/pages/viewpage.action?pageId=26837051. Accessed on: 28 May 2020.

38. International Health Terminology Standards Deveolpmnet Organisation *IHTSDO Advisory Group Manual* [Online]. Available from https://confluence.ihtsdotools.org/display/DOCAG/Advisory+Group+Manual. Accessed on: 25 May 2020.

39. SNOMED International *Advisory Group Structure Principles and Ways of Working* [Online]. Available from https://confluence.ihtsdotools.org/display/DOCAG/3+Advisory+Groups+Structure%2C+Principles+and+Ways+of+Working. Accessed on: 25 May 2020.

40. SNOMED International *The organization behind SNOMED CT* [Online]. Available from https://confluence.ihtsdotools.org/display/DOCSTART/14.+The+Organization+Behind+SNOMED+CT. Accessed on: 28 May 2020.

41. Regenstrief Institute Inc. *LOINC User Guide*. 2013. Available from: http://loinc.org/downloads/files/LOINCManual.pdf. Accessed on: 5/3/2013.

42. Regenstrief Institute Inc *Logical Observation Identifiers Names and Codes (LOINC®)* [Online]. Available from http://loinc.org/. Accessed on:
43. LOINC from Regenstrief *LOINC Committee* [Online]. Available from https://loinc.org/committee/. Accessed on: 8 June 2020.

44. LOINC from Regenstrief *LOINC User Forum* [Online]. Available from https://loinc.org/forum/. Accessed on: 10 June 2020.

45. LOINC from Regenstrief *Funding Support* [Online]. Available from https://loinc.org/funding-support/. Accessed on: 10 June 2020.

46. World Health Organization *FAQ Licensing ICD-10* [Online]. Available from https://www.who.int/docs/default-source/publishing-policies/who-faq-licensing-icd-10.pdf?sfvrsn=b2c8a69a_0. Accessed on: 14 May 2020.

47. World Health Organization *History of ICD,* [Online]. Available from https://www.who.int/classifications/icd/en/. Accessed on: 14 May 2020.

48. World Health Orgainization *World Health Assembly* [Online]. Available from https://www.who.int/about/governance/world-health-assembly. Accessed on: 15 May 2020.

49. World Health Organization *The World Health Organization Family of International Classifications* [Online]. Available from https://www.who.int/classifications/en/WHOFICFamily.pdf. Accessed on: 15 May 2020.

50. Australia Government. *Australia.gov.au*. 2012. Available from: http://australia.gov.au/. Accessed on: 3/3/2012.

51. The Commonwealth Fund *Health Care System and Health Policy in Australia* [Online]. Available from http://www.commonwealthfund.org/grants-and-fellowships/fellowships/australian-american-health-policy-fellowship/health-care-system-and-health-policy-in-australia. Accessed on: 16 January 2018.

52. European Observatory on Health Systems and Policies. Health Systems in Transition: Australia HiT Summary 2006. Available from: http://www.euro.who.int/__data/assets/pdf_file/0004/98824/E89731sum.pdf Accessed on:

53. Australian Institute of Health and Welfare. Australia's health 2016 2016. Available from: https://www.aihw.gov.au/reports/australias-health/australias-health-2016/contents/summary. Accessed on: 29/10/2020.

54. Joint Action to support the eHealth Network(JASEHN). Information Paper on Main eHealth activities outside of the EU Annex 2 Main Australia eHealth policies and activities 2017. Available from: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co17_en.pdf. Accessed on:

55. Australian Institute of Health and Welfare. *Australian Institute of Health and Welfare. (2016). About.* [Online]. Available from http://www.aihw.gov.au/about/. Accessed on:
56. Coalition of Australian Governments *About the Coalition of Australian Governments* [Online]. Available from https://www.coag.gov.au/about-coag. Accessed on: 17 January 2018.

57. Australian Digital Health Agency *About the Australian Digital Health Agency* [Online]. Available from https://conversation.digitalhealth.gov.au/about. Accessed on: 12 September 2017.

58. Australian Digital Health Agency. *Detailed Clinical Model Library*. 2017. Available from: https://developer.digitalhealth.gov.au/products/detailed-clinical-model-library. Accessed.

59. Australian Institute of Health and Welfare *METeOR home* [Online]. Available from https://meteor.aihw.gov.au/content/index.phtml/itemId/181162https://www.aihw.gov.au/reports/australias-health/national-health-data-dictionary-version-16/contents/table-of-contents. Accessed on: 29/10/2020.

60. Government of Australia *National Health Reform Act 2011* [Online]. Available from https://www.legislation.gov.au/Details/C2012C00542. Accessed on: 22 June 2020.

61. Council of Australian Governments *National Health Reform Agreement* [Online]. Available from https://www.federalfinancialrelations.gov.au/content/npa/health/_archive/national-agreement.pdf. Accessed on: 24 November 2020.

62. The University of Sydney *National Centre for Classification in Health* [Online]. Available from https://www.sydney.edu.au/health-sciences/ncch/icd-10-am.shtml. Accessed on: 24 November 2020.

63. Independent Hospital Pricing Authority *Organisational Structure* [Online]. Available from https://www.ihpa.gov.au/organisational-structure. Accessed on: 22 June 2020.

64. Australian Health Agency *Clinical Terminologies* [Online]. Available from https://www.digitalhealth.gov.au/get-started-with-digital-health/what-is-digital-health/clinical-terminology. Accessed on: 15 June 2020.

65. Australian Digital Health Agency *Australian National Terminology Licence Agreement* [Online]. Available from https://www.healthterminologies.gov.au/docs/DH_2400_2016_AustralianNationalTerminologyLicenceAgreement_v20160809.pdf. Accessed on: 18 June 2020.

66. Austalian Digital Health Agency *Australian Clinical Terminology User Group* [Online]. Available from https://www.healthterminologies.gov.au/learn?content=getinvolved. Accessed on: 26 June 2020.

67. SNOMED International *Australian Medicines Terminology* [Online]. Available from https://www.snomed.org/snomed-ct/case-studies/australian-medicines-terminology. Accessed on: 23 June 2020.

68. Austalian Digital Health Agency *Australian Medicines Terminology* [Online]. Available from https://www.healthterminologies.gov.au/docs/DH_2407_2016_AMT_FactSheet_v2.1.pdf. Accessed on: 23 June 2020.

69. Austalian Digital Health Agency *Australian Terminology Support Group* [Online]. Available from https://www.digitalhealth.gov.au/news-and-events/news/australian-medicines-terminology-amt-support-group-meeting. Accessed on: 23 June 2020.

70. PAHO eHEALTH *Canada eHealth Country Profile* [Online]. Available from https://www.paho.org/ict4health/index.php?option=com_content&view=article&id=9730:canada&Itemid=0&lang=en. Accessed on:
71. Parliament of Canada. *Parliamentary Institutions.* [Online]. Available from http://www.parl.gc.ca/marleaumontpetit/DocumentViewer.aspx?Sec=Ch01&Seq=2&Language=E Accessed on:
72. Health Canada. *Health Canada Health Care System* [Online]. Available from http://www.hc-sc.gc.ca/hcs-sss/pubs/system-regime/2011-hcs-sss/index-eng.php Accessed on:
73. Canada health infoway. *Canada health infoway – EHRS Blueprint – an interoperable EHR framework*. 2006. Available from: https://www2.infoway-inforoute.ca/Documents/EHRS-Blueprint-v2-Exec-Overview.pdf. Accessed on: 5/19/2011.

74. Global Digital Health Partnership (GDHP). Connect Health: Empowering Health Through Interoperability: GDHP White Paper on Interoperability 2018. Available from: https://www.gdhp.org/media-hub/news_feed/gdhp-reports. Accessed on:

75. and Gupta Chang.F, N. . Progress in electronic medical record adoption in Canada. *Canada Family Physician*. 2015; 61(12):[1076–84 pp.]. Accessed on:

76. Canada Health Infoway *About Canada Health Infoway* [Online]. Available from https://www.infoway-inforoute.ca/en/about-us Accessed on: 29/10/2020.

77. Canada health infoway. *Vision strategy advancing Canada's next generation of healthcare - 2015*. 2010. Available from: https://www2.infoway-inforoute.ca/Documents/Vision_Summary_EN.pdf. Accessed on: 7/5/2012.

78. Canada Health Infoway *Corporation Members* [Online]. Available from https://infoway-inforoute.ca/en/about-us/about-canada-health-infoway/corporation-members. Accessed on: 28 August 2020.

79. Morris K *Canadian Institute for Health Information Better data. Better decisions. Healthier Canadians* [Online]. Available from https://ncvhs.hhs.gov/wp-content/uploads/2018/07/Presentation-Canada-Health-Terminologies-and-Vocabularies-Morris.pdf. Accessed on: 28 August 2020.

80. Canadian Institute for Health Information *Board of Directors Governance Handbook, 2018* [Online]. Available from https://www.cihi.ca/sites/default/files/document/governance_handbook_en.pdf. Accessed on: 24 August 2020.

81. Canadian Institute of Health Information. Canadian Institute of Health Information - Access Data 2014. Available from: http://www.cihi.ca/CIHI-ext-portal/internet/EN/TabbedContent/standards+and+data+submission/data+requests/cihi012210. Accessed on:

82. Canadian Institute for Health Information *Codes and Classifications* [Online]. Available from https://www.cihi.ca/en/submit-data-and-view-standards/codes-and-classifications. Accessed on: 25 August 2020.

83. Canadian Institute for Health Information *ICD-11 (International Statistical Classification of Diseases and Related Health Problems, 11th Revision)* [Online]. Available

from https://www.cihi.ca/en/submit-data-and-view-standards/codes-and-classifications/icd-11. Accessed on: 25 August 2020.

84. SNOMED International *Canada* [Online]. Available from https://www.snomed.org/our-customers/member/canada. Accessed on: 18 August 2020.

85. Canada Health Infoway *Health Terminology Community* [Online]. Available from https://infocentral.infoway-inforoute.ca/en/collaboration/communities/health-terminologies. Accessed on: 20 August 2020.

86. eHealth Ontario *Digital Health Services* [Online]. Available from https://ehealthontario.on.ca/en/health-care-professionals/digital-health-services. Accessed on:
87. eHealth Ontario *eHealth Ontario. Whats an EHR?* [Online]. Available from https://www.ehealthontario.on.ca/en/ehrs-explained. Accessed on:
88. PrescribeIT *PrescribeIT. Canada's Electronic Prescription Service.* [Online]. Available from https://prescribeit.ca/component/edocman/165-prescribeit-patient-faq/view-document?Itemid=106. Accessed on:
89. Ocean eReferral Network. About eReferrals 2019. Available from: https://www.oceanereferralnetwork.ca/about/. Accessed on:

90. eHealth Ontario *EHR Connectivity Strategy* [Online]. Available from https://ehealthontario.on.ca/en/it-professionals/ehr-connectivity-strategy. Accessed on:
91. Canadian Instituite for Health Information(CIHI) *CIHI Reference Data Model* [Online]. Available from https://www.cihi.ca/en/submit-data-and-view-standards/methodologies-and-decision-support-tools/data-architecture-at-cihi. Accessed on: 29/10/2020.

92. World Health Organization. Ministry of Health New Zealand. Health Service Delivery Profile 2012. Available from: http://www.wpro.who.int/health_services/service_delivery_profile_new_zealand.pdf. Accessed on:

93. Ministry of Health *Digital health* [Online]. Available from https://www.health.govt.nz/our-work/digital-health. Accessed on:
94. New Zealand Ministry of Health *Digital Health 2020* [Online]. Available from http://www.health.govt.nz/our-work/ehealth/digital-health-2020. Accessed on: 20 Sep 2017.

95. Ministry of Health New Zealand. HISO 10083:2020 Interoperability roadmap: Driving the shift to a fully interoperable digital health ecosystem. 2020. Available from: https://www.health.govt.nz/publication/hiso-100832020-interoperability-roadmap. Accessed on:

96. Ministry of Health *Terms of reference for the Health Inforrmation Standards Organisation* [Online]. Available from https://www.health.govt.nz/about-ministry/leadership-ministry/expert-groups/health-information-standards-organisation/terms-reference-health-information-standards-organisation. Accessed on: 20 July 2020.

97. Health Information Standards Organisation *Health Information Standards Organisation* [Online]. Available from https://www.health.govt.nz/about-ministry/leadership-ministry/expert-groups/health-information-standards-organisation. Accessed on: 20 July 2020.

98. New Zealand Ministry of Health. Shared Care Record New Zealand. 2019. Available from: https://sharedcarerecord.org.nz/. Accessed on:

99. New Zealand Ministry of Health. New Zealand ePrescription Service. 2017. Available from: https://www.health.govt.nz/our-work/ehealth/other-ehealth-initiatives/emedicines/new-zealand-eprescription-service. Accessed on:

100. Ministry of Health *About the Ministry* [Online]. Available from https://www.health.govt.nz/about-ministry. Accessed on: 2 July 2020.

101. Ministy of Health *New Zealand Coding Convention* [Online]. Available from https://www.health.govt.nz/nz-health-statistics/classification-and-terminology/icd-10-am-achi-acs/new-zealand-coding-conventions. Accessed on: 10 July 2020.

102. Ministry of Health *New Zealand Clinical Coding Practice* [Online]. Available from https://www.health.govt.nz/nz-health-statistics/classification-and-terminology/icd-10-am-achi-acs/new-zealand-clinical-coding-practice. Accessed on: 13 July 2020.

103. Ministry of Health *National Minimum Dataset (hospital events)* [Online]. Available from https://www.health.govt.nz/nz-health-statistics/national-collections-and-surveys/collections/national-minimum-dataset-hospital-events. Accessed on: 5 November 2020.

104. Ministry of Health *SNOMED CT Implementation in New Zealand* [Online]. Available from https://www.health.govt.nz/nz-health-statistics/classification-and-terminology/new-zealand-snomed-ct-national-release-centre/snomed-ct-implementation-new-zealand. Accessed on: 2 July 2020.

105. Health Informatics New Zealand *Standards group looks to accelerate adoption of SNOMED* [Online]. Available from https://www.hinz.org.nz/news/411486/Standards-group-looks-to-accelerate-adoption-of-SNOMED.htm. Accessed on: 3 July 2020.

106. Ministry of Health *Guidelines for SNOMED CT Content Requests* [Online]. Available from https://www.health.govt.nz/system/files/documents/pages/guidelines-for-changes-to-snomed-ct-2019.pdf. Accessed on: 10 July 2020.

107. New Zealand SNOMED CT National Release Centre *SNOMED CT Content Request Service* [Online]. Available from https://www.health.govt.nz/nz-health-statistics/classification-and-terminology/new-zealand-snomed-ct-national-release-centre/snomed-ct-content-request-service. Accessed on: 6 July 2020.

108. New Zealand Universal List of Medicines *About The New Zealand Universal List of Medicines* [Online]. Available from https://info.nzulm.org.nz/about/. Accessed on: 9 July 2020.

109. Joint Initiative Council. Patient Summary Standards Set Guidance Document Version 1.0 2018. Available from: http://www.jointinitiativecouncil.org/registry/Patient_Summary_Standards_JIC_Jan_2018.pdf. Accessed on:

110. The Commonwealth Fund. *The English Health Care System.* 2020. Available from: https://international.commonwealthfund.org/countries/england/. Accessed.

111. NHS Digital *About NHS Digital* [Online]. Available from https://digital.nhs.uk/about-nhs-digital. Accessed on: 15 July 2020.

112. NHS Digital *Our leadership and governance* [Online]. Available from https://digital.nhs.uk/about-nhs-digital/our-leadership-and-governance. Accessed on: 15 July 2020.

113. NHS Digital *Our organisation structure* [Online]. Available from https://digital.nhs.uk/about-nhs-digital/our-organisation/our-organisation-structure. Accessed on: 15 July 2020.

114. NHXS *About us* [Online]. Available. Accessed on:
115. NHS Data Dictionary *OPCS Classification of Interventions and Procedures* [Online]. Available from http://www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/opcs_classification_of_interventions_and_procedures.asp. Accessed on: Apr 10th, 2017.

116. NHS Digital *NHS Data Model and Dictionary* [Online]. Available from https://datadictionary.nhs.uk/about/about.html. Accessed on:
117. NHS Digital. *Summary Care Record (SCR) in community pharmacy.* 2018.

118. NHS Digital *Electronic Prescription Service saves NHS £130 million over three years* [Online]. Available from https://digital.nhs.uk/article/7791/Electronic-Prescription-Service-saves-NHS-130-million-over-three-years. Accessed on: 30 January 2018.

119. NHS Digital *Electronic Prescription Service National Statistics* [Online]. Available from https://app.powerbi.com/view?r=eyJrIjoiZmRlZjY3MWItZDk2My00NTIxLWE5NmUtZDhiN2NjMDY2NjQ0IiwidCI6IjUwZjYwNzFmLWJiZmUtNDAxYS04ODAzLTY3Mzc0OGU2MjllMiIsImMiOjh9. Accessed on: 24 January 2018.

120. NHS Connect *GP Connect FHIR Landing Page* [Online]. Available from https://nhsconnect.github.io/gpconnect/overview_engage.html. Accessed on: 15 May 2017.

121. NHS Connect *GP Connect FHIR Resource Guidance* [Online]. Available from https://nhsconnect.github.io/gpconnect/development_fhir_resource_guidance.html. Accessed on:
122. NHS Digital *Terminology and Classifications* [Online]. Available from https://digital.nhs.uk/services/terminology-and-classifications. Accessed on: 31 July 2020.

123. NHS Digital *Management of Standards* [Online]. Available from https://digital.nhs.uk/services/terminology-and-classifications/clinical-classifications#management-of-standards. Accessed on: 21 July 2020.

124. NHS *OPCS Classification of Interventions and Procedures* [Online]. Available from https://www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/opcs_classification_of_interventions_and_procedures.asp?shownav=1. Accessed on: 28 July 2020.

125. NHS Digital *SNOMED CT Management* [Online]. Available from https://digital.nhs.uk/services/terminology-and-classifications/snomed-ct. Accessed on: 16 July 2020.

126. NHS Business Services Authority *Dictionary of medicines and devices* [Online]. Available from https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dictionary-medicines-and-devices-dmd. Accessed on: 28 July 2020.

127. NHS Digital *National Interim Clinical Imaging Procedure (NICIP) Code Set* [Online]. Available from https://digital.nhs.uk/services/terminology-and-classifications/national-interim-clinical-imaging-procedure-nicip-code-set. Accessed on: 30 July 2020.

128. NHS Digital *Welcome to the Request Submission Portal* [Online]. Available from https://isd.hscic.gov.uk/rsp/user/guest/home.jsf. Accessed on: 21 July 2020.

129. NHS Digital *GP Systems of Choice* [Online]. Available from https://digital.nhs.uk/services/gp-systems-of-choice. Accessed on: 28 July 2020.

130. NHS Digital *SNOMED CT in Primary Care* [Online]. Available from https://digital.nhs.uk/services/terminology-and-classifications/snomed-ct/snomed-ct-implementation-in-primary-care. Accessed on: 28 July 2020.

131. NHS England. *Five Year Forward View*. 2014. Available from: https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf. Accessed on: 08/01/2021.

132. National Information Board *Personalised Health and Care 2020 Using Data and Technology to Transform Outcomes for Patients and Citizens A Framework for Action* [Online]. Available from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/384650/NIB_Report.pdf. Accessed on: 31 July 2020.

133. Data Coordination Board *Standards Assurance Guidance* [Online]. Available from https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions. Accessed on: 23 July 2020.

134. NHS Digital *Information standards and data collections (including extractions)* [Online]. Available from https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions. Accessed on: 27 July 2020.

135. NHS Digital *Data Coordination Board* [Online]. Available from https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/data-coordination-board. Accessed on: 23 July 2020.

136. Government of England *Health and Social Care Act 2012* [Online]. Available from https://www.legislation.gov.uk/ukpga/2012/7/contents/enacted. Accessed on: 23 July 2020.

137. NHS Digital *Data Standards team* [Online]. Available from https://digital.nhs.uk/data-and-information/data-insights-and-statistics/data-standards-team. Accessed on: 27 July 2020.

138. NHS Digital *Diagnositics Data Service* [Online]. Available from https://digital.nhs.uk/services/diagnostics-data-service. Accessed on: 4 August 2020.

139. NHS Digital *Assurance Certificates* [Online]. Available from https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/assurance-certificates. Accessed on: 23 July 2020.

140. NHS Digital *Data Standards Assurance Service* [Online]. Available from https://digital.nhs.uk/data-and-information/data-insights-and-statistics/data-standards-team. Accessed on: 28 July 2020.

141. Dewing C Jones T , Steffensen SK. The Future of Patient Data A Danish Perspective 2018. Available from: https://www.futureofpatientdata.org/pdf/danish-perspective/The%20Future%20of%20Patient%20Data%20-%20The%20Danish%20Perspective%202018.pdf. Accessed on: 12/11/2020.

142. Trifork. One Patient - One National Medication Record 2019. Available from: https://trifork.com/?portfolio=fmk. Accessed on: 12/11/2020.

143. The Danish Health Data Authority. Healthcare in Denmark: An Overview 2016. Available from: www.sum.dk/~/media/Filer%20-%20Publikationer_i_pdf/2016/Healthcare-in-dk-16-dec/Healthcare-english-V16-dec.pdf. Accessed on: 12/11/2020.

144. MedCom. About MedCom. 2020. Available from: https://www.medcom.dk/medcom-in-english/about-medcom. Accessed on: 12/11/2020.

145. Schmidt SAJ Schmidt M, Adelborg K, Sundbøll J, Laugesen K, Ehrenstein V, Sørensen HT The Danish health care system and epidemiological research: from health care contacts to database records 2019. Available from: https://www.dovepress.com/the-danish-health-care-system-and-epidemiological-research-from-health-peer-reviewed-fulltext-article-CLEP. Accessed on:

146. Sundhedsdatastyrelsen. *Digital Health Strategy 2018-2022 'A Coherent and Trustworthy Health Network for All'* 2018. Available from: https://sundhedsdatastyrelsen.dk/da/diverse/download. Accessed on: 08/01/2021.

147. Kierkegaard P. eHealth in Denmark: A Case Study. *Journal of Medical Systems* 2013; 37. Accessed on:

148. Nordic Council of Ministers. eHealth standardisation in the Nordic countries 2019. Available from: http://norden.diva-portal.org/smash/get/diva2:1340369/FULLTEXT01.pdf. Accessed on: 12/11/2020.

149. Health Service Executive *About Us* [Online]. Available from https://www.hse.ie/eng/about/. Accessed on: 4 December 2017.

150. Irish Department of Health *eHealth Strategy for Ireland* [Online]. Available from http://www.ehealthireland.ie/Knowledge-Information-Plan/eHealth-Strategy-for-Ireland.pdf. Accessed on: 28 June 2018.

151. Health Service Executive *Office of the Chief Information Officer (OCIO)* [Online]. Available from http://www.hse.ie/eng/about/Who/OoCIO/. Accessed on: 4 December 2017.

152. Health Service Executive *Knowledge and Information Strategy* [Online]. Available from http://www.ehealthireland.ie/Knowledge-Information-Plan/Knowledge-and-Information-Plan.pdf. Accessed on:
153. Health Service Executive Ireland Access to Information Programme. *Healthlink Update October 2019.* 2019.

154. Health Service Executive Ireland *Information for the Public (IHI)* [Online]. Available from https://www.ehealthireland.ie/A2I-HIDs-Programme/Individual-Health-Identifier-IHI-/Information-for-the-Public/. Accessed on: 21 November 2019.

155. Health Service Executive Ireland *Latest Progress (IHI)* [Online]. Available from https://www.ehealthireland.ie/A2I-HIDs-Programme/Individual-Health-Identifier-IHI-/Latest-Progress/. Accessed on: 21 November 2019.

156. eHealthIreland *General eReferrals Data by Hospital Group* [Online]. Available from http://www.ehealthireland.ie/Strategic-Programmes/eReferral/Latest%20Data/Hospital-Groups/. Accessed on: 10/01/2019.

157. eHealth Ireland *Enterprise Architecture* [Online]. Available from https://www.ehealthireland.ie/Our-Team/Enterprise-Architecture/. Accessed on: 29/10/20.

158. eHealth Ireland *OoCIO Architecture Principles V2* [Online]. Available from https://www.ehealthireland.ie/Our-Team/Enterprise-Architecture/EA-Published-Documents/. Accessed on: 29/10/20.

159. eHealth Ireland Enterprise Architecture. HSE Design Authority ISF Programme ICT Asset Base Workstream 2.4 Standards Catalogue
2016.

160. Health Services Executive OCIO *Integrated Services Framework* [Online]. Available from https://www.hse.ie/eng/about/who/oocio/integrated-services-framework/. Accessed on: 29/10/2020.

161. eHealth Ireland Information Architecture *National Data Dictionary Metadata Registry Framework Briefing Paper* [Online]. Available from https://www.ehealthireland.ie/Our-Team/Enterprise-Architecture/Information-Architecture-/. Accessed on: 29/10/2020.

162. epSOS *OpenNCP General Presentation* [Online]. Available from https://openncp.atlassian.net/wiki/download/attachments/28311634/epSOS-OpenNCP-GeneralPresentation.pdf?api=v2. Accessed on: 2 February 2018.

163. Coyne E. *Irish Open National Contact Point As-Is Feedback informing HIQA Invitation to contribute to the development of Recommendations on the Implementation of a National Electronic Patient Summary in Ireland.* 2019.

164. SNOMED International *SNOMED CT: National Release Centre Guide - Requesting Changes* [Online]. Available from https://confluence.ihtsdotools.org/display/DOCNRCG/12.+Change+requests. Accessed on: Apr 10th, 2017.

Published by the Health Information and Quality Authority (HIQA).

For further information please contact:
Health Information and Quality Authority
George's Court
George's Lane
Smithfield
Dublin 7
D07 E98Y

+353 (0)1 814 7400
info@hiqa.ie
www.hiqa.ie