CONNECTED HEALTH: EMPOWERING HEALTH THROUGH INTEROPERABILITY

GDHP White Paper on Interoperability
Acknowledgements

The GDHP would like to thank the Chair of this work stream, Dr Don Rucker (National Coordinator for Health Information Technology, U.S. Department of Health and Human Services) and Co-Chair, Lynne Zucker (Executive Vice President, ACCESS Digital Health, Canada Health Infoway), for engaging GDHP participants in discussions, meetings and other activities to drive and develop this work. The GDHP would also like to thank member countries who participated in the Interoperability work stream discussions and in particular thank the countries who contributed their country profiles to this report – Argentina, Australia, Austria, Canada, Hong Kong SAR, India, Italy, Japan, Kingdom of Saudi Arabia, New Zealand, Portugal, Sweden, United Kingdom, United States and Uruguay. The GDHP Secretariat, including Professor Meredith Makeham, Rodney Ecclestone and Clara Lubbers, provided editorial support to the work stream Chair and Co-Chair, and collaborated closely with participant countries to ensure the development of this report.

We hope that this report provides both member and non-member countries with guidance on the key enablers required to work towards achieving an interoperable digital health ecosystem.

About the Global Digital Health Partnership

The Global Digital Health Partnership (GDHP) is a collaboration of governments and territories, government agencies and the World Health Organization, formed to support the effective implementation of digital health services. Established in February 2018, the GDHP provides an opportunity for transformational engagement between its participants, who are striving to learn and share best practice and policy that can support their digital health systems. In addition, the GDHP provides an international platform for global collaboration and sharing of evidence to guide the delivery of better digital health services within participant countries.
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Providing better care in order to help people live longer and healthier lives is the goal of governments and others delivering healthcare services around the world. Connected care through interoperable systems is key to that ambition. Healthcare facilities across the globe have made tremendous gains in shifting their record-keeping from paper to computerized systems that support this, however the path to widespread adoption has not always been a smooth one. Despite where any nation might be on the adoption spectrum, it is time to turn our attention to furthering the accurate and efficient transfer of health data in the form of interoperability.

The real importance of this work is in how connected care can best be used to improve the lives of our communities. Easy and secure exchange of standardized information will help services and consumers get the information, where and when they need it, to access, plan, deliver and coordinate services. Empowering patients by giving them access to their data allows them to better understand their care plan and facilitates coordinated care. Each country has different demographics, needs and capacity, yet we all struggle with siloed, disconnected information.

The Global Digital Health Partnership (GDHP) is working towards ensuring that widespread interoperability is possible on a global scale. This task would be easier if every nation had the same healthcare delivery system, with the same underlying infrastructure, and the same form of patient consent and participation. The reality is that every nation is different and it is through identifying, as well as understanding, these variations that we will arm both the GDHP and nations everywhere with the information needed to create a roadmap for achieving interoperability on an international level.

As you will read in the following paper, the GDHP undertook the task of collecting as much information from member nations as possible to understand not only their health system infrastructure, but also, if they exchange health data, for what purpose that exchange happens, and what standards are employed in the collection, use, and sharing of that data. I firmly believe that it will be through the use of common standards that we will achieve global alignment and the potential for international interoperability.

Through the efforts of the GDHP and this work stream we will continue to move closer to achieving the true goal of complete interoperability. This analysis of global health systems, as well the use of health standards, is just the start and the GDHP will continue to work towards true interoperability on a global scale.

Dr Don Rucker
National Coordinator for Health IT
U.S. Department of Health and Human Services

and

Chair, Interoperability
Global Digital Health Partnership
1 EXECUTIVE SUMMARY

1.1 BACKGROUND

The interoperability of clinical data is essential to high-quality, sustainable healthcare – this means that patient data is collected in standard ways and that it can be shared securely, in real time and with common meaning.

Effective interoperability of information is key to attainment of the health-related Sustainable Development Goals and to the improvement of the health and wellbeing of people across the world through the best use of evidence-based digital technologies. Interoperability is key to improving co-ordination of care services, equity of access to them, as well as their effective delivery. It improves prevention of communicable and non-communicable disease and supports optimal responses to population health priorities.

Interoperability ensures common meaning in a ‘connected up’ health system, and provides the data resources for development of innovative mobile digital services and ‘apps’ that can support the patient, citizen and the care professionals who serve them. Effective digital interoperability is a pre-condition for the realisation of the benefits of new clinical and data sciences – from genomics to machine learning - in health and care. Digital health can transform the outcome and experience of patients and citizens, but only if information is shared seamlessly.

Taking the opportunity to assess the interoperability landscape across GDHP member countries and territories allows consideration of how a greater degree of international collaboration could support improved national and regional implementation, and more harmonisation of data standards.

In 2018, on behalf of the Global Digital Health Partnership (GDHP), the Office of the National Coordinator for Health Information Technology (ONC) in the U.S. Department of Health and Human Services commissioned a global interoperability landscape review of GDHP member countries and territories. This analysis set out to inform the GDHP of interoperability related data exchange practices among its members, specifically related to how they exchange data and for what use the data is exchanged.

Fifteen countries and territories responded to the landscape analysis survey: Argentina, Australia, Austria, Canada, Hong Kong, India, Italy, Japan, New Zealand, Portugal, the Kingdom of Saudi Arabia, Sweden, the United Kingdom, the United States and Uruguay.

Analysis of the survey responses has revealed a number of key themes, and also significant diversity in terms of the interoperability status of individual respondent countries. A key objective in the review of country data has been to better understand the relationship between individual country drivers for achieving interoperability and their progress to date.
Interoperability is being achieved against a backdrop of many unique health systems and country-specific factors. Across the globe, despite progress and harmonisation, interoperability remains a significant challenge. The GDHP is in a unique position to reflect that, while interoperability will have many common approaches and benefits, these will be balanced differently in one region compared to another and that this has a significant impact upon the way challenges to interoperability maturity are being addressed.

1.2 KEY FINDINGS

The key themes, which centre on how countries exchange health data, for what purpose, and what role patients have in that process, are listed below:

- All 15 countries and territories use internationally recognised standards throughout their digital health systems;
- Semantic/code system standards ICD-10, LOINC®, and SNOMED CT® were adopted almost unanimously among the countries and territories that responded to the survey;
- HL7® standards and IHE profiles were most used to meet interoperability use cases;
- Fourteen of the 15 responding countries and territories provided an option for the patient to provide consent for the capture, use, or sharing of their digital health information;
- Patients are involved with their own health data, beyond consent processes, in thirteen of the 15 surveyed countries and territories; and
- Cost-effective and sustainable creation of national Health Information Exchange is essential and there is an opportunity for global harmonization and alignment through standards bodies such as IHE and HL7, which are used internationally; and
- FHIR® is rapidly emerging in many countries and territories as a next-generation interoperability standard.

As work within the Interoperability work stream progresses, the observations in this landscape analysis will help to provide guidelines for the creation of an interoperability maturity model, driving a more consistent international conversation and approach. This analysis can also assist the GDHP in providing a set of best practices for countries in achieving an interoperable health system.

1.3 RECOMMENDED NEXT STEPS

While there is a diversity of focus, priorities and progress, there are clearly many common (or highly similar) interoperability challenges, and all countries would clearly benefit from increased knowledge sharing and collaboration.

To that end, it is proposed that the following issues be further explored:

- **How can participants share lessons learned and reduce duplicated effort?**
  With many countries working on similar interoperability challenges, how can
countries who are further ahead in specific areas share the progress that they have made, and the lessons that they have learned?

- **How can participants collaborate to become better global buyers?**
  How can countries work together to present, where appropriate, a more unified set of international requirements to Health IT vendors, with the aim of driving down cost and decreasing time to market for Health IT solutions.

- How should standards alignment be addressed globally?

- **How can nations support, foster and cooperate with international standards development organisations?**

- **What one thing can participants collaborate on that would make a difference?**
  Is there an initial area where GDHP participants could work together to deliver value through increased collaboration and standardisation of approach? Would a globally harmonized and aligned FHIR®-based representation of medication lists be a good candidate for such collaboration?

“The drive for interoperability in the UK is to move away from this being a technical concept solely about standards but to be driven by the move to integrated care systems which ensure that interoperability is driven as part of this service change and not separate to it.

Furthermore, there is a strong drive to expose Open APIs from health and care systems (based on FHIR®) to establish ecosystems of apps that can utilise the data exposed and through SMART on FHIR® containers to enable simplified access to this information.”

United Kingdom response to Interoperability Landscape Survey

“There are varying levels of maturity in terms of digital capability across the New Zealand health sector. The Digital Health Strategy recognises that organisations are starting from different places, with different priorities, and will provide support relative to where an organisation is beginning from.

All New Zealand government funded health providers are required to develop a local digital investment plan in support of the national digital health strategy. Each health provider will be responsible for delivering their own plans but are expected to collaborate closely with their neighbours to reuse where possible and to reduce duplication.”

New Zealand response to Interoperability Landscape Survey
“The ONC Interoperability Standards Advisory (ISA) is the means by which ONC coordinates the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the healthcare industry to address specific interoperability needs including, but not limited to, interoperability for clinical, public health, and research purposes. It is regularly updated throughout the year, with a Reference Edition published at the beginning of each year to provide a ‘snapshot in time’ of available standards and implementation specifications for each listed interoperability need.”

United States response to Interoperability Landscape Survey

“Canada has a rich tradition of collaboration on national and international digital health standards and a record of fragmented implementation which often undermines standardization. As solutions are more globalized and domestic demand increases, Canada Health Infoway is looking for opportunities to deploy more digital health solutions at national scale and there is much to learn from other countries that have already accomplished this.”

Canadian response to Interoperability Landscape Survey

“Portugal is implementing widespread use of standards supported by many entities created for the purposes of interoperability and propagation of digital health systems. These efforts are based on a number of high level axioms that ensure a consistency of vision and approach.”

Portuguese response to Interoperability Landscape Survey

“Following a recommendation of the Federal Health Commission, Austria will use “Integrating the Healthcare Enterprise (IHE)” as the base standard for all future Healthcare IT projects, to achieve maximum international standardization, sustainability and cost-effectiveness.”

Austrian response to Interoperability Landscape Survey
2 INTRODUCTION: INTERNATIONAL OVERVIEW OF INTEROPERABILITY

Every day, hundreds of thousands of patients across the world experience transitions of care as they move between primary care physicians, hospitals, aged care facilities, allied health professionals and a variety of other healthcare contexts. The way in which their information is shared (or not shared, in many instances) has the potential to make the difference between high-quality, safe and efficient care, and poor-quality care which can result in adverse events and injury.

For this reason, interoperability is essential to digitally inclusive, safe, high-quality, efficient care. A lack of interoperability can pose a significant risk to patient safety and detract from high-quality, coordinated care.

Interoperability can be defined as:

The ability of a system or product to transfer meaning of information within and between systems or products without special effort on the part of the user. Interoperability is made possible by the implementation of standards.

2.1 WHY IS INTEROPERABILITY SO IMPORTANT?

The ability of different healthcare providers to use shared information with commonly understood meaning is a precondition for team-based, coordinated care, continuity of care, efficiency, data analytics, and positive patient experiences (1) (2) (3) (4). Exchanging high-quality data between multiple health systems, trusting that the meaning will be interpreted in the same way, requires interoperability (1) (2) (4).

The lack of interoperability between systems means healthcare providers often cannot exchange information effectively, which contributes to disjointed care, adverse events, inefficiencies and poor-quality data (5) (6) (7). Conversely, improvements in interoperability have direct benefits that are highly relevant to health consumers, carers and health and care providers:

- **Patient safety** – Every day in the health system, patient information is shared between health and care providers or, in some cases, critical information is not shared.

  When information is shared, an inability to clearly and unambiguously understand what was meant by other healthcare providers (particularly with respect to medications) in their medical records can result in adverse events, harming the safety of patients (8). Many of these are preventable through the sharing of information that is interpreted in the same way.
• **Coordination of care** – A lack of shared information, or a lack of confidence in the meaning of shared information, has a significant impact upon efforts to deliver team-based, integrated care.

Allowing health and care providers to quickly and easily share patient information will drive an increased focus on the importance of high-quality data and record keeping in an increasingly digital healthcare system. In turn, this will improve trust between health and care providers, creating a culture where coordinated, team-based models of care are common practice, underpinned by interoperability that works without being visible.

• **Efficiency of healthcare delivery** – Improved coordination of care will reduce time spent on unnecessary communication, remove unnecessary treatments, reduce adverse events and reduce repeated diagnostic testing.

Improvements in the sharing of appropriate patient health information will have a significant positive impact on the efficiency of healthcare delivery in each of these areas.

Successful interoperability is a complex endeavour. It relies not just upon the ability to share information between systems and people, but ultimately to have a common understanding of what that data means, and to be able to act upon it confidently to deliver the best possible care to patients.

Many healthcare stakeholders see interoperability as a technical exercise, focused on data types, data structures and complex standards developed by health informaticians who may be perceived as being separated from the realities of frontline healthcare.

Despite these common perceptions, interoperability could not be more important to improving healthcare outcomes.

There are a number of key elements that need to be in place to ensure good interoperability outcomes:

• **The ability to identify the patient with confidence** – through the use of standardised identifiers, or the ability to map local identifiers together with a high degree of confidence;

• **The ability to transmit the data securely to another health context** – either point-to-point secure messaging or through a Health Information Exchange (HIE), using an appropriate standard for data exchange;

• **Sufficient data quality** – to share data safely with other parties, and to act on data received, there must be a high degree of trust that the data is (where possible) complete, accurate and coherent;

• **The ability to understand what is meant by the data and its component parts** – using, where possible, data that is structured and coded (using an appropriate clinical terminology) such that its meaning is clear, and so that clinical decision support systems can be leveraged to provide additional quality and safety checking; and

• **The understanding that the sharing of data, and the delivery of treatment reflects the wishes and consent of the patient** – ensuring that no data is shared, or treatment undertaken, without the express consent of the patient and their carers.
A lack of standardised clinical processes and poor-quality, incomplete data, without structure and appropriate coding can result in an inability to understand with confidence what was meant by other healthcare providers. At best, this results in significant inefficiency. At worst, providers can make wrong decisions based on an incorrect understanding of diagnoses or medications, thereby causing harm.

The Interoperability work stream of the GDHP has focused upon identifying and mapping the healthcare outcomes that can and should be achieved through interoperability and on documenting the problems that can be solved. This will be achieved by documenting the current interoperability landscape (including use of standards, policy drivers, legal frameworks and supplier requirements), and then using this information to develop a meaningful work plan that drives consistency in international approaches to interoperability.

Ultimately, success will deliver tangible improvements to patient safety, coordination of care, and the overall quality of healthcare delivery.

2.2 SCOPE OF THIS REPORT

The scope of this report is to present a landscape analysis of the current state of digital health implementation and interoperability in each country and territory. From this analysis, the GDHP can begin to work together as a collective to determine policies, recommendations and guidelines for how best to achieve interoperability.

All GDHP countries and territories were invited to participate in the survey, and responses were received from 15 countries and territories including: Argentina, Australia, Austria, Canada, Hong Kong, India, Italy, Japan, New Zealand, Portugal, the Kingdom of Saudi Arabia, Sweden, the United Kingdom, the United States and Uruguay.

This analysis sets out to provide information about:

- Which GDHP countries and territories exchange health data electronically;
- How they exchange that data; and
- For what purpose the data are exchanged.

This report was developed by the GDHP Interoperability work stream. The working group is chaired by the United States and co-chaired by Canada.
2.3 METHODS USED

GDHP countries and territories were invited to contribute to the landscape analysis by responding to a survey on current interoperability and standards use and implementation. The survey asked the following questions:

1. Please describe your country’s digital health program.
2. Please describe your nation’s health information and communication technology or digital health infrastructure.
3. If your digital health system or infrastructure is centralized, describe how patients consent to their information being stored centrally or shared widely.
4. Please describe if and how health data are being exchanged within your nation.
5. For what purpose are the health data being exchanged?
6. Please describe the method used to exchange each health data type.
7. What standards are your country utilizing to enable data exchange? Please organize by type of health data as appropriate.
8. Does your nation utilize health information exchanges (HIEs), organizations that help enable health information exchange, if so how?
9. Please describe how patients are involved in the health data exchange process.
10. Do states/provinces/regions within your nation adhere to separate, or different, digital health policies? If so, how do they differ from the above responses?

See Appendix A for details of the participants who responded from each country.

The responses to these questions were synthesised and are presented in the discussion section of this report. A thematic analysis was then undertaken to draw out common themes and identify gaps described by GDHP participants.
3 RESULTS – INTERNATIONAL APPROACHES TO INTEROPERABILITY

3.1 RESPONSES FROM GDHP PARTICIPANTS TO SURVEY QUESTIONS

At the time of this report, there were a total of 23 participating countries and territories and the World Health Organization (WHO) in the GDHP. Fifteen countries and territories responded to the survey. Responses have been distilled and summarised from detailed responses, and in some instances may not fully reflect the significant underlying complexities and differences between national and regional, and public and private healthcare contexts.

Table 1, below, shows a high-level summary of key elements of the approach of countries and territories to interoperability:

<table>
<thead>
<tr>
<th>Country</th>
<th>For what purpose are health data being exchanged?</th>
<th>How are health data being exchanged / What standards are in use?</th>
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</table>
| Australia | • Continuity of care through the use of shared health summaries, discharge summaries, event summaries, eReferrals and specialist letters  
• Diagnostic imaging reports and results  
• Pathology reports and results  
• Electronic prescriptions | Currently, most bilateral exchange takes place using HL7® v2.4 or CDA®. My Health Record (the national electronic health record) primarily uses CDA® documents; however, it has a read-only FHIR® interface. |
| Austria | • Continuity of care through the use of discharge summaries and nursing reports  
• Diagnostic imaging reports  
• Laboratory reports  
• Patient medications – prescriptions and dispenses  
• Nursing care situation overview | The national eHealth Infrastructure ELGA architecture is in general following the profiles of “Integrating the Healthcare Enterprise (IHE)”:  
• Patient identification and demographics: PIXv3/PDQv3  
• Sharing clinical documents: Cross-Enterprise Document Sharing (XDS.b)  
• Sharing medication information: CMPD, PRE, DIS, PADV, PML  
• Access control and audit: ATNA  
• Healthcare Provider Authentication: XUA  
• Discharge Summaries and Nursing Reports: XDS-MS  
• Laboratory reports: XD-LAB |
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| Canada  | The most common use of stored electronic health information is to provide a single view of patient information, via a viewer to support clinical applications – transitions of care, acute, emergency, etc. | The following standards are used (endorsed by IHE profiles):  
- Transport standards: W3C (SOAP, HTTP), TLS, OASIS SAML, WS-Trust  
- OASIS ebXML for Cross-Enterprise Document Sharing  
- HL7® CDA® for nation-wide harmonized clinical documents  
- HL7® v3.x for patient-identification related communication  
- DICOM – international imaging standard (WADO)  
Terminologies & classifications used:  
- ICD-10, LOINC, Austrian terminologies (medicines, etc.) |
| Hong Kong | Focus is on supporting clinical care, improving clinical efficiency and improving quality and safety of care. Most major care processes are covered including: identifying patients; supporting transitions of care; prescribing medications; clinical ordering procedures and imaging; public health reporting; obtaining laboratory test results; viewing images; and safety alerts.  
The territory-based Electronic Health Record Sharing System (eHRSS) focuses on sharing records and also supports downloading allergy data to healthcare providers to protect patient safety. | HL7® v2 messaging is used for patient administrative events such as patient registration. HL7® CDA® R2 is used for exchanging clinical records such as allergies, prescriptions, clinical notes/summaries and laboratory results. |
<p>| India   | Currently the data collected from the patients are being used for public health management and surveillance purposes. However, with the Integrated Health Information Platform (IHIP) in place, the intention is to bring standardisation, homogeneity and interoperability in the capture, storage, transmission and use of healthcare information across various health IT systems. | To be completed. |
| Italy   | The Digital NHS features an Electronic Health Record (EHR) that enables telemedicine, electronic prescribing, and information and communication technology (ICT) integration among hospitals and primary care. | Within the EHR, the following standards are used for clinical data: ICD-9-CM, LOINC (Logical Observation Identifiers, Names and Codes), ATC, AIC. Death causes are coded using ICD-10, and hospitalisation records using ICD-9-CM. |</p>
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<td>Japan</td>
<td>Provision of high-quality medical care</td>
<td>There are 17 sets of such national standards, including seven master codes and standard formats for information exchange. Some of the examples for such master codes are Standard Master for Pharmaceutical Products (HOT reference numbers) and ICD-10 based Standard Disease Code Master for Electronic Medical Records. Two standard formats for information exchange are Standardized Structured Medical record Information eXchange (SS-MIX2) and Digital Imaging and Communications in Medicine (DICOM).</td>
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| New Zealand | New Zealand currently exchanges health information to support a variety of different clinical care purposes including, but not limited to: identifying patients; supporting transitions of care; prescribing medications; ordering procedures and imaging; public health reporting; obtaining laboratory/radiology results; and for population-based screening programs. | The following standards are in use across New Zealand:  
  - HL7® v2.x messages, FHIR®;  
  - HL7® CDA® documents (in a few cases only);  
  - Terminologies and classifications: LOINC, SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms), ICD-10AM/ACHI, New Zealand Medicines Terminology/Universal List of Medicines, GTIN; and  
| Portugal    | Health data exchange in Portugal is relevant to the following use cases:  
  - Patient Identification  
  - Patient summary  
  - Electronic prescriptions and dispensations  
  - Chronic medication  
  - Clinical exams and results  
  - Imaging studies requests and appointments  
  - Allergies and Intolerances data exchange  
  - Vaccination card and status  
  - Administrative workflow data (admissions, discharges and transfers)  
  - Referral requests and appointments | Exchange standards:  
  - HL7® v2.5  
  - HL7 FHIR®  
  - HL7® CDA® documents  
  - Terminologies and classifications:  
    - LOINC  
    - SNOMED CT  
    - ICD-9, ICD-10  
    - CPARA (Portugal’s Catalogue of Allergies and Other Adverse Reactions)  
    - CPAL (Portugal’s Catalogue of Laboratorial Analysis) |
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<td>Kingdom of Saudi Arabia</td>
<td>The Kingdom of Saudi Arabia currently has no Health Data Exchange, however, some of the standards and indicators related to continuity of care include: patient identification; provider/organisation management; coded lab orders; coded lab results; medication dispensation; medication prescription; encounter summaries; surgical notes; baby discharge summaries; mother discharge summaries; general purpose discharge summaries; sharing diagnostic imaging; referral request/response; tele-radiology reporting; immunisation records.</td>
<td>There are a variety of standards that are used to facilitate data exchange across the U.S. These are often dictated by individual use cases, organisational or governmental policies or requirements, and/or by EHR capabilities. Some examples of standards or implementation specifications supporting push and query-based exchange, include: SOAP-based secure transport; direct transport; eHealth exchange specifications; IHE standards such as Cross-Enterprise Document Reliable Exchange (XDR), Cross-Enterprise Document Sharing (XDS) and Patient Care Device (PCD); ISO standards such as ISO/IEEE 11073, Continua Design Guidelines (ITU H.810, H.811, H.812, H.812.5, H.813), HL7® standards including Version 2 and FHIR®. For more information about the various exchange capabilities and associated standards and implementation specifications, Section III of the Interoperability Standards Advisory (ISA) (9) contains the most up-to-date information.</td>
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<tr>
<td>United States</td>
<td>The U.S. currently uses health information exchange for a variety of different clinical care purposes including, but not limited to: identifying patients; supporting transitions of care; prescribing medications; ordering procedures and imaging; public health reporting; obtaining laboratory test results; and obtaining images. Health insurers in the U.S. actively engage in data exchange to verify patient identity and pay for and invoice for the necessary services. In addition, exchange between health care providers (or intermediaries working on their behalf) and patients occurs to provide patients access to key components of their health records.</td>
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| United Kingdom | • Patient identification – between organisations and in interactions with national services  
• Transfers of care – national standards exist for acute, Accident & Emergency and mental health eDischarges and letters from outpatient clinics  
• Record level transfers of information between care settings  
• Radiology  
• Imaging  
• Pathology | A range of standards are currently in use:  
• HL7® v2.x – extensive local use;  
• HL7® v3 – use for existing national components such as GP summary, Personal Demographic Service etc.;  
• HL7® FHIR® – for newer specifications (note that the current interoperability policy specifies FHIR® as the default methodology for use; any requests which do not use FHIR® must be justified to the business interoperability design authority);  
• Bespoke XML – used for several secondary uses collections;  
• READ codes – previously used terminology for general practice which has been deprecated but is still present in records;  
• SNOMED CT – the primary clinical terminology;  
• dm+d (dictionary of medicines and devices) – the primary national drug terminology;  
• ICD-10 – used across secondary uses collections and within some records;  
• ICD-11 – the UK is participating in the ICD-11 field trials as a WHO-FIC release centre;  
• Transport standards – various standards including W3C (SOAP and others), ebXML (OASIS), HTTP, TLS, SMTP, FHIR® RESTful APIs;  
• DICOM – international imaging standard; and  
• IHE – various IHE standards are deployed by local organisations and regional structures though there is no national implementation. |
| Uruguay      | Continuity of care                                                                                                   | Health information exchange is based on the IHE XDS profile, with document repositories run by each health provider.  
Clinical documents are exchanged based on HL7® CDA® R2 standard, with strong use of clinical terminologies such as SNOMED CT, LOINC and WHO classifications. |
The following table shows a high-level, aggregated view of the use of key standards areas in participating countries. Clearly, the full set of standards in use in participating countries is more complex and nuanced than reflected below, and some survey responses have omitted to note the use of specific standards. However, this representation should assist in making initial, high-level comparisons about areas of standards usage. The Working Group proposes that this table form the foundations of an interactive, web-based version, allowing drill-down to additional detail and narrative in each country and standards area.

Table 2: High-level summary of standards usage across GDHP Interoperability work stream participants

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<th>Country</th>
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<td>HL7® v2</td>
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3.2 INTEROPERABILITY APPROACHES IDENTIFIED FROM GDHP CONSULTATIONS

3.2.1 ARGENTINA

Argentina has recently published the National eHealth Strategy 2018-2024. The strategy defines the rules for the Interoperability of clinical systems: enabling the sharing of clinical information for clinical, epidemiological and statistical purposes.

Argentina’s health system has a fragmentation that reflects the great diversity of health information systems platforms used by healthcare providers in the public and private sectors.

The National eHealth Strategy defines a set of standards that enable communication between different providers, in the context of a National Interoperability Network. This network enables data transmission between healthcare providers, including the National Ministry of Health, without a central clinical data repository. Only traditional statistical and epidemiological databases are maintained at the federal level. These central, purpose-specific, databases existed before the implementation of the interoperability network. The new standards-based mechanism simplifies the process of data submission, achieving better quality of data.

The National infrastructure of the Interoperability Network uses standards to enable communication between participating health information systems:

- **Identity Federation**: facilities for creating links between local patient identification numbers, using the national level as a bridge. This process is based on IHE PIX profile (Patient Identifier Cross-Referencing) and FHIR interfaces.
- **Sharing clinical documents**: providers share clinical content to support continuity of care. Documents structured as FHIR resources, following guidelines that define the requirements for a set of clinical documents types. Documents are shared using the FHIR based IHE MHD profile (Mobile access to Health Documents). Clinical content is represented using SNOMED CT. The first document to be shared in the network is the patient summary, based on the IPS - International Patient Summary initiative.
- **ePrescription**: providers store prescriptions in local prescription repositories. Using the National Interoperability Network pharmacies can retrieve and update prescriptions, marking each use. The system uses HL7 FHIR APIs and resources, and a SNOMED extension that is mapped with the National Medications Dictionary.
- **Supporting national registries for statistics and epidemiology**: Specific sets of resources and APIs are used to submit information to the national level. Some statistical information is converted from SNOMED CT to ICD-10 for statistical processing.

At the beginning of 2019, the National Patient Identifier Cross-Referencing system went live enabling, provinces and private providers to make the first step of integrating standards for public health reports and sharing an Electronic Patient Summary for clinical care.
3.2.2 AUSTRALIA

In 2018, the Australian Digital Health Agency (the Agency) launched a new digital health strategy titled Safe, Seamless, and Secure: evolving health and care to meet the needs of modern Australia (10).

Australia’s National Digital Health Strategy has seven strategic priority areas for delivery outlined in the 2018–22 plan, and provides a clear plan for collaboration and action to improve health outcomes for all Australians. These priorities include the My Health Record system (a secure online summary of a patient’s key health information for every Australian), secure messaging, interoperability and data quality, medication safety, enhanced models of care, workforce education, and driving innovation.

These priorities are operationalised through a Framework for Action (11) that identifies required activities and the roles of stakeholders. In addition, work is underway to develop a targeted interoperability strategy for Australia in 2019.

Australia’s universal health system is jointly funded and delivered by federal government, who largely provide primary and out-of-hospital care services, and state and territory governments, who largely provide hospital services. A nationally available online patient-controlled summary healthcare record exists for all citizens, called the My Health Record system, operated by the Australian Digital Health Agency. This system is able to collect information from any registered healthcare provider using securely connected conformant software. In this way, it provides a patient-centric common point for the sharing of healthcare information.

The My Health Record system is a CDA®-based document repository with capacity to store a broad range of document types including, but not limited to (12): shared health summaries (curated by General Practitioners); eReferrals; specialist letters; discharge summaries; event summaries; prescription and dispense records; and diagnostic imaging and pathology reports.

By the end of February 2019, every eligible Australian will receive a My Health Record, unless they tell the Agency that they do not want one during a five-month opt-out period that began on July 16, 2018.

Once a patient has a record, access controls can be applied (at the patient’s discretion) in order to protect access to the record with a PIN code, or to limit access to individual documents.

More broadly, with regard to health data, each state and territory government holds public hospital and public community service information within jurisdictional data stores. All states and territories have a degree of fragmentation of data across multiple internal systems, with variable internal interoperability. Some jurisdictions have developed capacity to provide clinicians with integrated views across internal systems.
One jurisdiction has integrated record viewing accessible by clinicians in the community context (13).

Within Australia, substantial volumes of data are exchanged, on a point-to-point basis, between healthcare providers who have a clinical relationship to each other and a shared patient. For example, most pathology laboratories provide information directly back to referring general practitioners (GPs) in electronic formats.

When a GP clinical information system and a laboratory exchange data, they typically do so using a bilaterally agreed terminology and payload definitions. To date, many of these bilateral agreements have organically sprung into being with a large number of variations between them, meaning that there are idiosyncrasies in message content and terminology definitions.

Currently, bilateral information exchanges primarily support pathology results, imaging reports, specialist referrals, and associated reports and letters. Discharge summaries from public and private hospitals are also sent using these bilateral exchange providers where possible. Where not possible, discharge summaries are sent via fax or mail. Prescription exchanges are in operation but are not universal in coverage.

As part of National Infrastructure (key digital health infrastructure systems and services), the Australian Government operates the National Healthcare Identifiers Service. This service allows the allocation, management and look up of three types of unique identifiers:

- Individual Healthcare Identifier (IHI) – used to identify the people who are the subject of care;
- Healthcare Provider Identifier – Individual (HPI-I) – used to identify the clinician who provided care; and
- Healthcare Provider Identifier – Organisation (HPI-O) – used to identify the organisation under which care is provided.

Most jurisdictions and private providers of care have capacity to link their internal patient identifiers to the IHI.

The Australian Digital Health Agency also operates the National Clinical Terminology Service (NCTS) (14). This service provides national reference terminology to industry in easily computable formats. The NCTS’s terminology solutions include SNOMED CT-AU and the Australian Medicines Terminology (AMT). Tools and services available to users include: a terminology server (with a FHIR® interface), an online terminology browser, a terminology mapping platform and a National Syndication Server (for clinical terminology content distribution). The NCTS is accessible via FHIR® APIs (15).
3.2.3 AUSTRIA

As member of the European Union, Austria’s Digital Health Program originates from a call of the European Commission in 2004 to its member states to provide a national eHealth strategy. In response, the “Austrian eHealth Initiative” developed this strategy in 2005, announcing that eHealth must be patient-centric, cross-organisation, maintain patient privacy and data security, and be based on the highest degree of standardisation.

As an immediate action, in 2006, the three main Austrian stakeholders in health (the federal entity, all nine Austrian provinces and the Austrian Social Insurance) founded the ELGA project “elektronische Gesundheitsakte”, electronic health records) to create a nationwide, patient-centric EHR serving as backbone to all future eHealth applications.

Following the first three recommendations for the strategy, ELGA was designed to be patient-centric, cross-organizational and accompanied by a specialized ELGA law which focuses especially on all patient privacy and data security concerns.

Austria’s current Digital Health Program is framed by overarching “Digital Austria agenda”\(^1\). It is tightly connected to Austria’s eGovernment strategy and aligned with Europe’s Digital Agenda “Europe 2020”, which drives the establishment of a “Digital Single Market (DSM)\(^2\).”

The ELGA law\(^3\) was enacted by the Austrian Parliament in 2012 and regulates points such as voluntary (opt-out) participation of citizens (of whom three per cent have opted out) and the mandatory participation of healthcare providers. The opt-out policy allows patients to object to the creation of data, object against access to data, view documents and view an access log.

Austria’s national infrastructure will be connected to the European Digital Service Infrastructure for eHealth (eHDSI) in the coming years, to ensure cross-border exchange of health data with the other European member states.

The architecture of ELGA provides a number of centralized components, such as

- Master Patient Index;
- Healthcare Provider Index;
- Access Control System, Audit and Logging;
- the ELGA Patient’s Portal (https://www.gesundheit.gv.at) and
- the e-Medication database for patient’s medications.

However the majority of clinical data is stored decentralized and at the point of creation, except for certain dedicated applications, such as e-Medication and (upcoming) e-Immunization.

ELGA areas are technically IHE (Integrating the Healthcare Enterprise) XDS Affinity Domains according to the IHE Cross-Document Sharing (XDS) profile, which allow sharing

\(^{1}\) https://www.digitales.oesterreich.gv.at/
\(^{2}\) https://ec.europa.eu/digital-single-market/
\(^{3}\) See online version in English language at https://www.ris.bka.gv.at/Dokument.wxe?Abfrage=Erv&Dokumentnummer=ERV_2012_1_111
and retrieving of clinical documents within the scope of the respective domain, but also by other ELGA areas using the IHE Cross-Community Access (XCA) profile.

A detailed description of the ELGA architecture can be found here: ELGA Architecture

The national eHealth Infrastructure ELGA architecture generally follows the profiles of “Integrating the Healthcare Enterprise (IHE)” and the international standards endorsed by those.

- **IHE Profiles used:**
  - Patient identification and demographics: PIXv3/PDQv3
  - Sharing clinical documents: Cross-Enterprise Document Sharing (XDS.b), XCA
  - Sharing medication information: CMPD, PRE, DIS, PADV, PML
  - Access control and audit: ATNA
  - Healthcare Provider Authentication: XUA
  - Discharge Summaries and Nursing Reports: XDS-MS
  - Laboratory reports: XD-LAB

- **International standards used (endorsed by IHE profiles):**
  - Transport standards: W3C (SOAP, HTTP), TLS, OASIS SAML, WS-Trust
  - OASIS ebXML for Cross-Enterprise Document Sharing
  - HL7® CDA® for nation-wide harmonized clinical documents
  - HL7® v3.x for patient-identification related communication
  - DICOM – international imaging standard (WADO)

- **Terminologies & classifications used:**
  - ICD-10
  - LOINC
  - Austrian terminologies (medicines, etc.)
  - HL7® v2.x is used for interoperability within healthcare facilities

Health data are intended to be exchanged mainly over the ELGA infrastructure, but alternative health data exchange mechanisms in Austria as still in place and include peer-to-peer transmission of laboratory and radiology results and reports.

To move services onto the ELGA infrastructure, ELGA has recently introduced the “ELGA plus” program, which allows the usage of the infrastructure within a closed group of stakeholders for special purposes.

A program running on “ELGA plus” is following the basic legal regulations of ELGA, but is independent of the constraints of the specific ELGA law and thus allows the usage of the ELGA infrastructure even if purpose-specific consent policies are required (e.g. that the specific application is an optional service and operated on a patient’s consent-based policy, or in turn that the patient is not allowed to opt-out because the application is part

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4 See more details on the underlying standards in question “What standards is your country utilizing to enable data exchange? Please organize by type of health data as appropriate”.
of its treatment process). This concept will enable Healthcare Providers to run regional report request/transmission as mentioned above.

ELGA currently covers 71 percent of government hospitals, 87 percent of total beds, and 25 percent of other hospitals. Selected primary care providers are able to read the ELGA. The system also covers 5.5 million registered patients with 99.5 percent unique ID coverage, while 3.2 percent of the population have opted out.

There have been two million physician discharge summaries and 613,000 nursing discharge summaries derived from the ELGA. In addition, 6.1 million laboratory reports and 2.9 million radiology reports have been generated. The next application on the infrastructure is e-Immunization, which will replace the paper vaccination pass of all Austrian citizens and include: electronic recording of vaccines administered; immunization status; notification about pending vaccinations; and analysis of data for public health.

Alternative health data exchange mechanisms in Austria include peer-to-peer transmission of laboratory and radiology results and reports.

Future planned applications are the sharing of more document types (e.g. outpatient reports, pathology reports, etc.), a patient summary and the sharing of medical images.

The national eHealth Infrastructure ELGA architecture generally follows the profiles of IHE, in particular, profiles from the IHE Domains IT Infrastructure, Patient Care Coordination and Pharmacy

Following a recommendation of the Federal Health Commission, Austria will use "Integrating the Healthcare Enterprise (IHE)" as the base standard for all future Healthcare IT projects, to achieve maximum international standardization, sustainability and cost-effectiveness.

All future eHealth applications on ELGA are intended to be developed on the base of IHE profiles if available. In the case that no IHE profile exists for the intended interoperability use case, the creation of such a profile is supported by Austria in tight cooperation with the IHE Development Domains.

Patients were involved during the conception phase of ELGA, and are the owners of their health data and in full control of granting access rights according to the opt-out rules in the ELGA law. The ELGA portal allows patients full access to all of their clinical information within the ELGA; however, clinical data are currently created by healthcare professionals only (not by the patient).
3.2.4 CANADA

Canada Health Infoway (Infoway) helps to improve the health of Canadians by working with partners to accelerate the development, adoption and effective use of digital health across Canada. Through its investments, it helps to improve access to care, quality of care, and the efficiency of the health system. Established in 2001, Infoway is an independent, not-for-profit organisation funded by the federal government.

While Infoway has the mandate to accelerate uptake of digital health across the country, the organisation works closely with partners that have complementary mandates. 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. Provincial and territorial digital health delivery organisations provide leadership and deliver solutions in their respective jurisdictions.

Shortly after it was established, Infoway began working with the provinces and territories to build the components of an Electronic Health Record (EHR): client and provider demographics; diagnostic images and reports; dispensed medication history; laboratory test results; clinical reports; and immunisation history. Infoway made investments in creating the EHR capability in each province and territory, as well as investing in the adoption of electronic medical records (EMRs), telehealth and other point-of-care solutions.

Recently, Infoway launched a national electronic prescribing service, called PrescribeIT™. This is the first national data exchange service, with FHIR®-based integration to prescriber EMRs, pharmacy management systems, and interoperability with registries and databases managed by the provinces and territories. This is the first time that Infoway has taken the role of directly managing a digital health service.

Consent has not been tackled at the national level as most health services are still managed by the provinces and territories.

Various provincial and regional viewers facilitate in-context access to EHR information. In all cases, these are leveraged for clinical use and, in a few provinces, these are also accessible via a patient or citizen portal.

Clinical, administrative, drug, and diagnostic data are exchanged provincially, territorially and federally. Methods of data exchange vary and include the use of HL7® v2 messages, HL7® v3 messages, CDA®, FHIR® and XDS.

Recently, there has been a significant shift from the use of traditional HL7® messages to the use of HL7® FHIR® and APIs in Canada.

The most common use of stored electronic health information is to provide a single view of patient information, via a viewer to support clinical applications – transitions of care, acute, emergency, etc.

Canada initially focused on EHRs with information about patient medications, laboratory and radiology results, clinical notes, and a range of other valuable patient information available to authorised clinicians. Clinician point-of-care solutions are increasingly integrating with provincial/territorial EHRs with the provinces/territories operating the health information exchanges (HIEs).
The Canadian e-prescribing service, PrescribeIT, transmits prescriptions from prescribers to pharmacies, and is currently in limited production release in two provinces with the objective of establishing a national solution. This HIE service is managed by Infoway.

The newest initiative, being run by Infoway, is called ACCESS Health. This will establish a national HIE specifically to accelerate citizen access to personal health information and digital health services. This HIE is expected to be in limited production in the first half of 2019 and is expected to use a cloud-based infrastructure, a FHIR® based API service and a blockchain enabled consent service.

Canada has a rich tradition of collaboration on national and international digital health standards and a record of fragmented implementation which often undermines standardisation. As solutions are more globalised and domestic demand increases, Canada Health Infoway is looking for opportunities to deploy more digital health solutions at national scale and there is much to learn from other countries that have already accomplished this.
3.2.5 HONG KONG

The Hong Kong Hospital Authority (HA) manages 43 public hospitals and institutions, providing over 90 per cent of inpatient service to Hong Kong. HA started with a green fields environment in 1990, and in 1995 HA first deployed the Clinical Management System (CMS) – a comprehensive, integrated, interoperable EMR deployed across the whole of Hong Kong extending from primary to convalescent and community care. Focus is on supporting clinical care, improving clinical efficiency and improving quality and safety of care. In 2000, the electronic patient record (ePR) was implemented to provide a consolidated view of patient data from all public hospitals in one single platform.

From 2000 to 2010, HA continued to roll out digitised solutions to Hong Kong hospitals and launched Hong Kong-wide radiological image sharing, sharing detailed records with the private sector. Through CMS phase III, HA became “filmless” in 2009. The next big iterations in the HA digital strategy included the 2010 launch of end-to-end inpatient medication order entry (IPMOE), dispensing and administration system. In 2016, patients could also book their specialist outpatient appointments via mobile app. Since 2017, HA has been working to implement a fourth phase of the CMS and a second iteration of the Electronic Health Record Sharing System (eHRSS), Hong Kong’s equivalent of a territory-wide HIE.

The CMS is an essential clinical tool to support public clinical services for the entire population of Hong Kong. The CMS manages data for 11 million patients, holding data on 380 million episodes of care, two billion laboratory results, 423 million radiology studies, and 723 million drug items. The system on average completes 14 million transactions per day and holds three petabytes of data, while also maintaining a 99.98 per cent uptime.

CMS is a comprehensive, integrated, interoperable EMR deployed across the whole of Hong Kong extending from primary to convalescent care. Its focus is on supporting clinical care, improving clinical efficiency and improving quality and safety of care. Most major care processes are covered including: identifying patients; supporting transitions of care; prescribing medications; clinical ordering procedures and imaging; public health reporting; obtaining laboratory test results; viewing images; and safety alerts. The patient app supports patients to book appointments and remind patients about attendance.

In 2016, HA – as the technical agent of the Hong Kong SAR Government – launched the territory-wide eHRSS so that both public and private health sectors can share their patient data with explicit and informed patient consent.

eHRSS is an opt-in system which patients may voluntarily participate in. Patients have to give consent that allows the Commissioner for the Electronic Health Record to obtain from, and to provide to, for healthcare and referral purposes, any prescribed healthcare providers (to whom the patients had given sharing consent) the sharable data of that person in eHRSS.

The eHRSS is developing a patient portal to allow patients to access and enter their health data, and to define who can access their record. The health data entered will be shared to eHRSS. Similar development is also being undertaken at HA and the health data entered will be shared with CMS.

Data are exchanged between the eHRSS core infrastructure and healthcare providers based on HL7® message standards, either through web services or regular batch
interfaces. The data are stored in central data repositories to ensure performance, security and availability.

Patient identification is based on the Hong Kong Identity Card issued by the Immigration Department.

HL7® v2 messaging and CDA® R2 are being used for data exchange. HL7® v2 messaging is used for patient administrative events such as patient registration. HL7® CDA® R2 is used for exchanging clinical records such as allergies, prescriptions, clinical notes/summaries and laboratory results.
3.2.6  INDIA

India has a mixed system of healthcare consisting of a large number of hospitals run by the Central Government, the state governments, as well as by the private sector. Health infrastructure includes 156,231 sub-centres, 25,650 primary health centres, 5,624 community health centres, and more than 600 districts hospitals. There are 476 medical colleges in India. However, the level of use of ICT in the healthcare sector in the country is lower in comparison to other countries.

At the same time, both union and state governments are working on several fronts to make use of the opportunities offered by ICT. Private sector hospitals are also in the process of implementing ICT projects, including EHRs and adopting international standards. As per the planning commission report of 2012, the situation is worse for the poor as they cannot afford healthcare at high rates from private sector providers, which currently serve 78 per cent of outpatients and 60 per cent of inpatients.

India has diverse healthcare needs across a wide network of public health facilities, with several national health programs covering communicable and non-communicable diseases, and a strong focus on maternal and child health. At the same time, only 18 per cent of people in urban areas of the country are covered under any kind of health insurance scheme (either government or private).

The National Health Policy (2017) referred to a digital health technology ecosystem, recognising the integral role of technology (eHealth, mHealth, cloud, Internet of Things, wearables, etc.). To deliver healthcare, a National Digital Health Authority (NDHA) will be set up to regulate, develop and deploy digital health across the continuum of care.

Several reforms in the health sector after 2014 moved towards universal health coverage and to reduce out-of-pocket expenditure. One such program is the Digital India Initiative, aiming to transform India into a digital empowered society and knowledge economy. This program is planned in multiple phases from 2014 to 2018.

The Ministry of Health and Family Welfare (MoHFW) has also released a concept note discussing establishment of the National eHealth Authority (NeHA) in India. NeHA will be the nodal authority for eHealth services in India. MoHFW published EHR standards for India in 2013 and updated them in 2016. MoHFW has been a member of the International Health Terminology Standards Development Organization (now SNOMED International) since April 2014 to support the affordable and consistent use of vocabularies through Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) for widespread adoption in India.

The Government of India set up a Centre for Health Informatics (CHI) under the eHealth Division of MoHFW to initiate several digital health initiatives in the country, and started the National Health Portal (NHP) as a citizen portal with the objective of improving the health literacy of the masses in India. CHI also initiated and monitored various digital health interventions such as online registration systems, mCessation program, various mHealth applications for patients, health helplines, ‘Mera Aspataal’ (feedback portal for hospital services), My Health Records, and eRaktkosh.

Many corporate hospitals in India have reached HIMMS Level 6 certification (Healthcare Information and Management Systems Society). Currently less than 2.5 per cent of hospitals in the Asia-Pacific have reached Level 6. At Level 6, the patient can access records over the internet and hospitals have implemented a patient satisfaction tracking survey to measure patient satisfaction.
The Indian digital health system faces a number of challenges. These include information technology (IT) systems with data in silos and a lack of hardware and connectivity readiness. With the aim of furthering India and Australia’s long-standing partnership, the two countries recently signed a Memorandum of Understanding (MoU) envisioning greater cooperation and collaboration in the health sector, and strengthening digital health in India along with several other public health priorities. At the same time, the WHO adopted India’s resolutions on digital health at the recent World Health Assembly 2018.

Currently, digital health infrastructure in India is federated in terms of public (at national and state level) and private healthcare. Even between private hospitals and health insurance providers, digital health infrastructure is fragmented and interoperability does not occur except the sharing of a few patient details.

The Indian National Health Policy suggests exploring the use of “Aadhaar” (unique ID) for identification, as well as the creation of registries (i.e. patients, provider, service, diseases, document and event) for enhanced public health/big data analytics, creation of an HIE platform and national health information network, use of the National Optical Fibre Network and use of smartphones/tablets for capturing real-time data — key strategies of the National Health Information Architecture. HL7®, ICD-10, MDDS, DICOM 3.0, LOINC (Logical Observation Identifiers, Names and Coding) and SNOMED CT are major considerations in developing EHR standards for India.

Currently, patients are not involved in or do not provide consent for digital health information storage and sharing between relevant authorities. However, the recommendations from the National Knowledge Commission’s working group proposed the development of an Indian health information network to introduce a common national EHR with minimal dataset and a uniform standards-based system for EHRs.

There are many EMR, EHR and health information systems (HIS) currently in place in hospitals and patient data is locked within these systems and can’t be exchanged with other healthcare service providers. An HIE would facilitate the exchange of patient-level data with other healthcare service providers.

To provide interoperability of the various EHR systems already implemented, an Integrated Health Information Platform (IHIP) is being set up by the MoHFW. The primary objective of IHIP is to enable the creation of standards-compliant EHRs for citizens on a pan-India basis, along with the integration and interoperability of EHRs through a comprehensive HIE as part of this centralised platform.

Shared Health Records (SHRs): The IHIP intends to build single shared longitudinal health records of patients in due course by harmonising the clinical information that is being collected from multiple EHR/HIS systems (both current and prospective). The SHR system will provide a centralised repository to store and manage the health information that is shared by the heterogeneous information systems (HIS, EHR, MCTS, Nikshay etc.) that function across India. The HIE should have the capability to parse the health data into the SHR.

An HIE platform would be able to analyse all participating systems and facilitate data exchange in a standard format from multiple formats (i.e. API, HL7®, etc.). The system should have the flexibility to take data in batch mode or real-time mode based on the need and status of the peripheral systems.
Apart from IHIP, the recent EHR guidelines also recommended following international and national standards:

- HL7®, ICD-10, MDDS, DICOM 3.0, LOINC, SNOMED CT; a defined list of supporting/complementing standards – ISO and interoperability standards.

- To achieve interoperability at this level, standardising vocabularies, or mapping between different vocabularies may be necessary.


- Functional requirements: ISO/HL7® 10781:2015 (Health Informatics).

- Reference model and composition: ISO 13940 (Health informatics – System of concepts to support continuity of care) and ISO 13606 (Health informatics – Electronic health record communication), openEHR Foundation Models Release 1.0.2.

- Coding System: LOINC test, measurement and observations. WHO Family of International Classifications (WHO-FIC) including ICD, ICF, ICHI, ICD-O.


- Personal healthcare and medical device interface: IEEE 11073 health informatics standards and related ISO standards for medical devices.


- Digital Certificate: ISO 17090 (Health informatics - Public key infrastructure) (parts 1–5).
The Italian National Health System (NHS) Digital Policy is focused on an eHealth strategic innovation objective at the national level. This objective is contained in the Strategy for Digital Growth 2014–2020. Specific funding has been allocated in order to support policy and digital delivery services.

Some examples of the digitisation of processes in the healthcare sector are the care pathways provided for the citizen:

- The start of the care path takes place through the general practitioner (GP), which is supported by an EHR, telematic disease certificates and e-prescription;
- Outpatient assistance, where supporting tools are the “territorial booking system” and EHR;
- Hospital assistance, which is supported by the EHR and dematerialisation; and
- The post-acute phase, caring for citizens through local services, supported by the EHR and telemedicine.

According to the General Data Protection Regulation (GDPR), individual data (e.g. racial or ethnic origin, religious beliefs, genetic data, biometric data intended to uniquely identify a natural person, and data related to the health or sexual orientation of the person) can be processed in the case that:

- Treatment is necessary for purposes of preventive medicine or occupational medicine, assessment of the employee’s ability to work, diagnosis, assistance or health or social therapy, or management of health or social systems and services on the basis of EU law or of the member states or in accordance with the contract with a health professional (Article 9(2)(h) of the EU regulation) and the professional must be subject to professional secrecy (Article 9(3) of the EU regulation); and
- Treatment is necessary for reasons of public interest in the public health sector, such as protection against serious cross-border threats to health or the guarantee of high standards of quality and safety of healthcare and of medicinal products and medical devices, on the basis of EU or member state law (Article 9(2)(i) of the EU regulation).

When these conditions occur, the consent of the interested party is not required.

Data are produced locally within healthcare institutions and exchanged between these and between the regions. Interchange also takes place between the regions and the central level – the Ministry of Health or, for specific research and/or surveillance activities, directly from healthcare institutions to national and regional surveillance systems, for example the Italian Health Institute (ISS).
The EHR allows each citizen to have always at their disposal their own health and social health information. The EHR can be accessed through personal credentials, via smartcard or through SPID credentials. SPID is the digital identity card for citizens: a single credential system, with a verified identity, that can be integrated on public and private websites according to the SAML standard.

For the EHR, the patient must express two consents:

- Consent to the feeding of the EHR, required to include the data and documents related to the provided services in the record – in the absence of such consent, the EHR remains empty and can therefore not be used either for treatment purposes or for research and government purposes; and

- Consent to consultation using EHR, required to make the data accessible to health professionals who will take care of the patient – in the absence of such consent, the EHR can be used only for governmental and research purposes, taking any precautions to not allow direct reference to the identity of the patient.

However, it should be clarified that the lack of consent to consultation using EHR does not affect access to medical treatment.

Consent must be formulated in clear language and indicate that the data that flows into the record are related to the current (or past) state of health of the relevant party. The consent must also indicate that it is necessary to express two distinct consents on the EHR, and that the EHR will be accessible for the purposes of treatment to the healthcare staff who will take over care of the patient.

The patient has the right to request the obscuring of health and social health data and documents both before and after entry into the EHR.
3.2.8 JAPAN

Japan is building a nation-wide network to share electronic medical records among healthcare providers, which aims to help clinicians to provide optimal healthcare services and to lengthen healthy life expectancy through the introduction of data and technological innovations. The network is being planned for operation towards the 2020 financial year. Improving interoperability is one of the key enablers of the reform.

In Japan each healthcare provider manages its electronic health record system, and the interoperability between different systems has been promoted. At the local level, some areas have developed health record networks as a result of voluntary efforts by healthcare institutions and local governments since the 2000s. The Ministry of Health, Labour and Welfare (MHLW) is currently taking steps to develop a nationwide network among healthcare providers to share patient medical information. In doing so standardisation of medical information and improvement in compatibility are some of the key challenges.

The Health Information and Communication Standards Board (HELICS) verifies draft standards in the field of healthcare recommended by the academia or by associations of vendors. The MHLW reviews these standards, authorises them as national standards, and then promotes their use. There are 17 sets of such national standards, including seven master codes and standard formats for information exchange. Examples of such master codes include Standard Master for Pharmaceutical Products (HOT reference numbers) and ICD-10 based Standard Disease Code Master for Electronic Medical Records. Two examples of standard formats for information exchange are SS-MIX2 storage and DICOM.
3.2.9 NEW ZEALAND

Health and disability services in New Zealand are delivered by a complex network of public and private organisations and people. Each has their role in working with others across the system to achieve better health for New Zealanders.

In terms of public healthcare delivery, there are 20 District Health Boards (aligned to 4 regions) that take the lead for planning, procuring, and delivering healthcare services to their populations.

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 our health provider identifier) for associating care events to a specific individual.

The New Zealand Health Strategy was developed in 2016 and lays out the challenges and opportunities facing the New Zealand health sector and describes the future New Zealand wants, including the culture and values that will underpin this future. It recognises the opportunities that technology provides and highlights “what great could look like in 2026”.

In 2017 New Zealand developed a Vision for Health Technology to guide how we use technology to 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. It outlines how New Zealand will collectively seize opportunities and mitigate risk, sets out priorities for action and describes how we can measure the value delivered from investment in digital health services. Interoperability is identified as a key enabler. The Digital Health Strategy is currently in the advanced stages of development.

There are varying levels of maturity in terms of digital capability across the New Zealand health sector. The Digital Health Strategy recognises that organisations are starting from different places, with different priorities, and will provide support relative to where an organisation is beginning from.

All New Zealand government-funded health providers are required to develop a local digital investment plan in support of the national Digital Health Strategy. Each health provider will be responsible for delivering their own plans but are expected to collaborate closely with their neighbours to reuse where possible and to reduce duplication.

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There is no plan for centralisation of infrastructure within the New Zealand health sector, except for the delivery of the core foundational services (e.g. national health identifiers, API development platform, FHIR® and terminology servers, etc).

Healthcare data (clinical and non-clinical) are exchanged between provider organisations. The exchange of data for clinical referrals, orders, discharges, prescribing and dispensing, results management, etc. primarily use the HL7® v2.x messaging standard with small pockets using HL7® CDA® (e.g. ePrescriptions and patient data transfer between general practice) for document exchange. Typically, data that are sent to the Ministry of Health for operational performance and clinical pathway monitoring is exchanged using file transfer technologies.

Electronic data exchange between primary care and secondary care and secondary care to secondary care (and tertiary/quaternary) is increasing, especially with respect to referrals and discharge letters/documents, and diagnostic results.

The majority of data exchange between New Zealand 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.

The New Zealand health system and its infrastructure are not centralised but do have a series of regulations and rules that govern how health data are shared. The New Zealand Privacy Act (18), Health Information Privacy Code (19), and New Zealand Health and Disability Act (20) all govern how, when, and for what purpose health data can be exchanged between parties. Data transfer of personal health information is primarily governed by a consent model at the point of capture and patients have the option of opting out.

In addition, NZ healthcare data exchange is covered by a set of principles for interoperability (21). These principles centre on consumer trust, no unreasonable blocking of access to information, data sharing to support clinical decision-making, conformance with standards and the use of common capabilities. Health providers and their industry partners are asked to make a commitment to these principles. Their commitment is enacted via a Vision and Charter for Interoperability (22) published in 2016.

There are a number of standards published by the New Zealand Health Information Standards Organisation (HISO) (23) related to capturing and exchanging data electronically in order to enable semantic interoperability. These standards cover clinical document metadata, security and privacy requirements, terminology standards, laboratory and radiology orders and results, eReferrals, and medicines and medical devices. HISO is currently facilitating the review and update of a number of standards related to interoperability and working on developing adoption roadmaps for them.
The following interoperability and data exchange standards are in use across New Zealand:

- HL7® v2.x messages, FHIR®;
- HL7® CDA® documents (in a few cases only);
- Terminologies and classifications: LOINC, SNOMED CT, ICD-10AM/ACHI, New Zealand Medicines Terminology/Universal List of Medicines, GTIN; and
- Web standards: SOAP, REST.

In 2010, New Zealand embarked on an initiative to give patients access to their personal health information held by primary care organisations (specifically general practice). More than 58 per cent of New Zealand general practices offer patient portals and 13% of patients have enrolled for access.
3.2.10  PORTUGAL

Digital health interoperability in Portugal is currently based on three pillars. **LiGHt (Local Interoperability Gateway for Healthcare)** is a middleware system responsible for the communication between applications within an institution. **PNB (Portuguese National Broker)** is responsible for central interoperability and the communication with other government entities. For instance, when a child enrolls in school, there is a verification process that goes through PNB channels to assess whether the child’s immunisations are up to date. **NCP (National Contact Point)** is responsible for communication with other countries, for instance, by sharing clinical summaries.

In the current scenario, LiGHt’s approach is to use HL7 v2.5 to communicate with local systems and HL7 FHIR to integrate with the central broker (PNB), which in turn utilises HL7 FHIR in its integrations with other systems. NCP then uses HL7 FHIR to communicate with the central broker (PNB), delivering and receiving HL7 CDA to and from foreign countries. In terms of HL7 FHIR profiling, technical specifications are written in plain text by a FHIR profiling team and shared with the business analysts and developers who will use interoperability services in their products. Locally, administrative and financial management data are already exchanged through interoperability channels in HL7 v2.5.

In order to improve service quality in the future, it is planned that by 2022, the adoption of HL7 FHIR will be widened and strengthened by building fundamental blocks such as a FHIR server and a terminology server to better standardise the semantics involved in health data exchange. The main purposes can be described as follows:

1. Facilitating the development process of integration validations in HL7 FHIR across the interoperability ecosystem to:
   - Ensure conformance of the messages produced by systems with defined profiles and terminologies.
   - Facilitate integration of new profiles with the HL7 FHIR Standard.
   - Propagate profile sharing in a common knowledge base.
   - Propagate API sharing and reuse to the community in general.

2. Automating integration tests to:
   - Allow cost reduction associated with the development and realization of tests with several stakeholders.
   - Automate tests creation processes, saving time.
   - Eliminate failures inherent to human interactions and repetitive tasks.
   - Ensure a process quality increase, hence by developing products less susceptible to failures.

3. Certify products with the NHS’s interoperability platform to:
   - Ensure integration conformance, in which the software provider shall demonstrate technical conformance of its product with interoperability platform requisites, by sending evidences of this conformance.
   - Make available technical specifications in the in-house HL7 FHIR development platform with the ability to validate its structure.
• Ensure that integration tests are made successfully based on the aforementioned automatic tests.
• Issue a conformance certificate after the evidences and associated documentation are concluded and accepted by the interoperability team.
• Ensure integration quality.
3.2.11 KINGDOM OF SAUDI ARABIA

The Kingdom of Saudi Arabia’s 2030 healthcare vision includes an eHealth strategy as a key focus, ensuring all facilities have digital health capabilities. Part of that focus includes extending broadband across the Kingdom of Saudi Arabia and strengthening the current digital transformation.

By 2020, the goal is to provide a unified health record to 40 per cent of the Kingdom’s population. This record will provide a lifetime longitudinal view of all health-related data for each individual. The eHealth Solutions Framework is the backbone of the Kingdom of Saudi Arabia’s digital health system and illustrates the full range of IT solutions and capabilities necessary to develop a complete and robust unified health record. By default, this system will use an opt-in model.

The current digital health infrastructure is a combination of centralised and federated, with good interoperability within an enterprise but limited interoperability between enterprises. Not all facilities (hospital, primary healthcare and ancillary services) have digital health infrastructure, which is currently being rolled out with plans to have this available to all facilities by 2020.

There is no current health data exchange, but a contract for Saudi eHealth Exchange (SeHe) and Saudi Health Insurance Bus (SHIB) has recently been signed. The project timeline is 11 years with multiple phases.

Health data exchange will occur through registries, payment gateway, terminology services, management console, clinical data repositories, document repositories, patients and providers portals, eligibility and claims and payments management, and insurance portal. All data will be stored centrally.

The initial use cases for SeHe are: patient identification; provider/organisation management; coded lab orders; coded lab results; medication dispensing; medication prescription; encounter summaries; surgical notes; baby discharge summaries; mother discharge summaries; general purpose discharge summaries; sharing diagnostic imaging; referral request/response; tele-radiology reporting; and immunisation records.

Interoperability standards and policies (25) are available for review.

The Health Service Bus (HSB) establishes the system-to-system integration channel to access services implemented by the SeHe-SHIB program. The HSB offers a standards-based integration mechanism to the various healthcare and data management systems.

A key function of the HSB is to map messages from one format to another data format, mapping across protocols, and data enrichment. It is expected that each HIE and EHR repository integrated to the SeHe and the SHIB platform will provide a set of services that will allow a user to submit a request for an EMR of a patient.

Communication services will provide all the necessary services to connect and send and receive messages in the appropriate standard formats between all applications connected to the platform. It will allow point-of-service applications to connect and access, put, or use information in the data and document repositories in a controlled manner.
One component of SeHe is the Patient Portal. The Patient Portal is a web-based application that enables patients to interact with SeHe to access their (or their dependants’) EHR as well as management of the patient’s (or his/her dependants’) record within the Patient Registry. The Patient Portal will also host basic preference management for the communication with SHIB (notification).
3.2.12 SWEDEN

Sweden has a decentralised organisation for providing healthcare and digital healthcare services.

There are three levels of administration: national government (whose role is to establish principles and guidelines, and to set the overall political agenda for Swedish healthcare); county councils and regions (of which there are 21, whose responsibility is to organise healthcare in such a way that all citizens have access to good care); and municipalities (of which there are 290, responsible for care for the elderly, care for persons with physical and mental disabilities, support and services to persons who have completed therapy and been discharged from hospital, and for school healthcare).

In 2016, SALAR (the Swedish Association of Local Authorities and Regions, an organisation that represents Sweden’s municipalities, county councils and regions) and the government made an agreement to support efforts to digitise social services and healthcare and endorsed a common vision for eHealth 2025 (27).

The vision comes with an action plan (28) that identifies regulatory frameworks, more consistent use of terminology and classification, and standards as fundamental conditions for enabling the eHealth vision.

Sweden has a decentralised infrastructure when it comes to digital health information systems. This is due to the levels of administration as described above. Each county council is responsible for its own digital health system and there can be several different systems in a county council.

There is a national platform provided by Inera (29). Inera is a company owned by Swedish county councils, regions and municipalities. The Inera platform offers services to the county councils and municipalities as well as to private healthcare providers. It is not mandatory to use any of the services and the county councils and municipalities decide for themselves which services they want to connect to. The platform uses the following standards:

<table>
<thead>
<tr>
<th>For organisational interoperability:</th>
<th>For semantic interoperability:</th>
<th>For technical interoperability:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Continua guidelines (and IHE)</td>
<td>• HL7 v2</td>
<td>• W3C XML Schema</td>
</tr>
<tr>
<td></td>
<td>• HL7 v3 Green DCA</td>
<td>• W3C XML Schematron</td>
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<td></td>
<td>• HL7 v3 RIM</td>
<td>• HTTPS/TLS</td>
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<td></td>
<td>• HL7 FHIR</td>
<td>• OASIS WS-I Basic Profile</td>
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<td>• OASIS DocBook</td>
<td>• OASIS SAML Profiles</td>
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<td></td>
<td>• OASIS SAML</td>
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<td>• SNOWMED CT</td>
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<td>• ISO 20601</td>
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<td>• Continua (and IHE)</td>
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<td>• ICF</td>
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7 SALAR’s list of county councils and regions (in Swedish),
https://skl.se/tjanster/kommunerlandsting/landstingochregionerlista.1247.html
The e-prescription system is a national system. The Swedish eHealth Agency (the Agency) (30) is responsible for providing the IT services needed for prescribing and filling out the e-prescriptions. The Agency also keeps the national registers that hold all necessary information to support the e-prescription system. For example, the e-prescription repository and the national pharmaceutical sales statistics. The system providers connect to the Agency’s services and incorporates them into their own system.

Patients must consent to have their prescriptions stored electronically, but there is no consent needed from the patients for the prescriptions to be sent to the e-prescription repository. If a patient doesn’t want their prescriptions to be stored electronically, he or she will handle paper prescriptions instead. Only pharmacists and the patients themselves can access the information.

A new law, National Medication List, was passed in June 2018 (31). This law will allow healthcare professionals, pharmacists and patients to share nationally stored information about prescribed and dispensed drugs, which is not possible under the current laws. This law will come into full effect in 2020 and will replace current laws described above. The registers and IT services needed to access the national medication list are being built by the Swedish eHealth Agency and they will be mandatory to use by all healthcare providers and pharmacies.

The Patient Data Act (2008) (32) enables healthcare employees, with the patient’s consent, to gain electronic access to patient records from different care providers across organisational boundaries.

The patient has a right to prohibit, or block, their information from being shared – there are two levels of prohibition. The patient can block healthcare professionals outside a clinic (inner level) or outside a healthcare provider (outer level) from getting access to the information.

Patients can access their own data, although depending on where the data is stored it must be accessed in different ways.

Information from EHR systems can be accessed from an e-service called My Journal via 1177.se, a portal that Inera provides. All county councils and regions can have access to the portal and can provide their patients with their own health data. The patients do not have to provide consent to access their own information, which can only be accessed by using a secure e-ID. The patients can, however, lock the journal from being accessible through the e-service.

How much information a patient sees when using the service varies between county councils. It also varies between different medical clinics. Some EHR systems can’t populate the portal with information due to inoperability difficulties.

The handling of personal information is regulated by the EU’s General Data Protection Regulation (GDPR). All other laws and regulations regarding the administration or use of
health data are national. Different county councils, regions and municipalities can choose their own solution to adhere to the regulations.
3.2.13 UNITED STATES

The United States has an advanced, but segmented, digital health program. Through the use of rule-making and regulation, the U.S. Government has influenced the adoption and use of health IT, specifically EHR systems, and is in the process of doing the same with the concept of interoperability. The Office of the National Coordinator for Health Information Technology (ONC) is the main government body tasked with regulating health IT or digital health in the U.S. Many other government bodies both interact with and influence the digital health ecosystem in the U.S. Some have programs or regulations that can have an impact on health IT developers such as: Centers for Medicare & Medicaid Services (CMS), the Department of Justice (DoJ), the Food and Drug Administration (FDA), and the Office for Civil Rights (OCR). The Government also has separate departments or agencies that purchase systems including the Department of Defense (DoD), the Indian Health Service, and the Department of Veterans Affairs (VA). Finally, there are agencies that fund research related to digital health such as the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health.

The American Recovery and Reinvestment Act (ARRA) of 2009 included a provision known as the Health Information Technology for Economic and Clinical Health (HITECH) Act (33) which, among other things, created incentive programs for the adoption and use of certified EHR technology (34). These were administered by CMS and called the Medicare and Medicaid EHR Incentive Programs. In addition, HITECH gave ONC authority to create and administer a certification program, which stipulates requirements for certified EHR technology that EHR developers worked to meet, and created mechanisms to certify that EHR developers met those criteria. Eligible hospitals and eligible professionals (e.g. physicians, nurse practitioners) across the nation would then attest to CMS that they were using a certified EHR and would receive incentive payments as part of their Medicare-Medicaid reimbursement payments. This effort was also known as the Meaningful Use Program and evolved over time with several iterations of the certification specifications.

As of 2015, 96 per cent of hospitals and 78 per cent of physician offices use certified EHR technology. In short, a significant majority of individuals in the United States now have a digital footprint of their health and care experience, generating new sources and uses of this electronic health information every day (50).

While the use of EHRs is now ubiquitous across the U.S., electronic health data still remain mostly in institutional silos. Data are largely not shared across providers, except for limited sharing through state or regional health information exchanges or among providers that use a single developer system. In addition, there are reports that some institutions will not share health data or make it difficult to share data for commercial or proprietary reasons.

For these reasons, in 2016 Congress passed the 21st Century Cures Act (Cures Act) (35), to help ensure that EHRs are interoperable and health data can easily be shared across systems, healthcare providers, and with patients. The law creates penalties for any private entities that attempt to engage in information blocking – failing to allow patients or physicians to retrieve information from within a given system – and requires the use of published application programming interfaces (APIs) without special effort. This means data within the EHR should be retrievable by other authorised applications or health IT
products without requiring the requesting product to have to implement any special coding or retrieval mechanisms. The Cures Act also requires ONC to develop and implement the foundation and communication lines that allow health data to flow freely. This has been named the Trusted Exchange Framework and Common Agreement (TEFCA), currently under development, which will outline a common set of principles for trusted exchange and minimum terms and conditions for trusted exchange. The TEFCA is designed to bridge the gap between providers’ and patients’ information systems and enable interoperability across disparate health information networks (36).

Currently, the infrastructure in the U.S. is federated (i.e. each provider deploying its own EHR software and each community and state determining whether to develop health information exchanges). Healthcare providers across settings use EHRs which include numerous functionalities, including: provider order entry; electronic prescribing; calculation of clinical quality measures; providing clinical decision support; capacity to exchange electronic health information with other providers (i.e. transitions of care) and integrate such information from other sources; and more.

A majority of EHR systems enable the electronic exchange of health information through the processes of patient admission, discharge or transfer, billing, electronic prescribing, and/or summary of care record exchange. With the advent of the Cures Act and the advance in technology there has been increased adoption of HL7® FHIR® to enable API-based forms of data exchange. As the health system continues to evolve and the Cures Act provisions are implemented, the hope is the digital health ecosystem will be more centred on APIs and the use of the pathways outlined in the TEFCA.

The U.S. digital health system and its infrastructure are not centralised, but do have a series of regulations and rules that govern how health data are shared. The Health Insurance Portability and Accountability Act (HIPAA) largely governs the protection, transmission, and use of health data. Generally, health data can be shared between healthcare providers and relevant business associates (e.g. health insurers) as long as it is done for the purpose of treatment, payment, or healthcare operations. Thus, healthcare providers and business associates may exchange health information with another provider for treatment purposes, without needing patient consent or authorisation (see 45 CFR 164.506(c)(2)) (37). However, state regulations related to consent do vary widely, and the inconsistencies across states may hinder exchange of health information between parties across state lines (38). In addition, under HIPAA, individuals (patients) have a right to a copy of their records in their preferred format, provided the format is readily available at a given healthcare provider. The U.S. Department of Health and Human Services Office for Civil Rights is charged with enforcing HIPAA.

Health data are being exchanged within the U.S., though exchange approaches vary widely. ONC measures national progress related to interoperability based upon providers’ engagement in four aspects of interoperability: electronically sending, receiving, querying and integrating data from external sources. Summary of care records serve as a common method used to exchange health information, and thus measurement of interoperability has focused on assessing levels of summary of care exchange.
The U.S. currently uses health information exchange for a variety of different clinical care purposes including, but not limited to: identifying patients; supporting transitions of care; prescribing medications; ordering procedures and imaging; public health reporting; obtaining laboratory test results; and obtaining images.

Health insurers in the U.S. actively engage in data exchange to verify patient identity and pay for and invoice for the necessary services. In addition, exchange between healthcare providers (or intermediaries working on their behalf) and patients occurs to provide patients access to key components of their health records.

Exchange of health data across the U.S. is facilitated by a variety of methods, including directed or “push” exchange, query-based exchange, and API-based exchange. Generally, these will be dictated by the individual use case and, in some cases, will vary by receiving system requirements (i.e. state or local health department jurisdictions).

As a general rule, push or directed exchange will be used in cases where a known recipient or destination system endpoint exists, for use cases such as transitions of care or referrals, public health data submission, electronic prescribing, medical device communication, image exchange, or quality reporting. In cases where information may exist in numerous or unknown locations, query-based exchange is used to find relevant information across the healthcare system. In many cases, this will be limited to information or specific documents (e.g. C-CDA®) that has been provided to a health information exchange (HIE) or health information organization (HIO) by other participants. There are emerging use cases where API-based exchange will be used to find specific information in EHRs and extract relevant data elements as part of queries.

A variety of standards are used to facilitate data exchange across the U.S. These are often dictated by individual use cases, organisational or governmental policies or requirements, and/or by EHR capabilities.

Some examples of standards or implementation specifications supporting push and query-based exchange, include: Simple Object Access Protocol (SOAP)-based secure transport; direct transport, eHealth exchange specifications, IHE standards (39) such as Cross-Enterprise Document Reliable Exchange (XDR), Cross-Enterprise Document Sharing (XDS) and Patient Care Device (PCD), ISO standards such as ISO/IEEE 11073, Continua

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The ONC Interoperability Standards Advisory (ISA) (9) is the means by which ONC coordinates the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the healthcare industry to address specific interoperability needs including, but not limited to, interoperability for clinical, public health, and research purposes. It is regularly updated throughout the year, with a Reference Edition published at the beginning of each year to provide a “snapshot in time” of available standards and implementation specifications for each listed interoperability need.
A recent national survey reports that as of 2017, half of individuals had been offered access to online health records by either a healthcare provider or insurer (40). Online health records can be in the form of a portal that provides access to view their provider’s EHR, health-related data shared via a secure website by their health insurer, or personal health records (41), which may include data from multiple providers. Half of individuals who were offered access to their medical information accessed their data within the past year; this represents approximately three in 10 individuals nationwide. Informal caregivers play an important role in the management of health and healthcare for many individuals. Almost one in five individuals cared for or made healthcare decisions for someone with a medical or behavioural condition or disability in 2017. Approximately one-quarter of these caregivers electronically accessed their care recipients’ health records within the past year.

Individuals have a legal right to request a copy of their medical record from their healthcare provider or health plan. The Privacy Rule generally requires HIPAA-covered entities (health plans and most healthcare providers) to provide individuals, upon request, with access to the protected health information (PHI) about them in one or more “designated record sets” maintained by or for the covered entity. This includes the right to inspect or obtain a copy, or both, of the PHI, as well as to direct the covered entity to transmit a copy to a designated person or entity of the individual’s choice. Individuals have a right to access this PHI for as long as the information is maintained by a covered entity, or by a business associate on behalf of a covered entity, regardless of: the date the information was created; whether the information is maintained in paper or electronic systems onsite, remotely, or is archived; or where the PHI originated (e.g. the covered entity, another provider, the patient, etc.) (42).

Providing individuals with easy access to their health information empowers them to be more in control of decisions regarding their health and wellbeing. Additionally, patients can ask for their health record to be shared with an organisation or mobile application (app) of their choice.

Patients today primarily have electronic access to a view of part of the information in their physician’s EHR through what is referred to as a “patient portal”. Patient portals typically offer access to medication lists, laboratory results, vaccination records, and after-care visit summaries. Patient portals also have other functionality such as allowing messaging with the doctor, nurse, or provider organisation, as well as requesting prescription refills or scheduling appointments. Guidance was released by ONC to help patients navigate this world and assist them in retrieving their data (43). In 2017, 52 per cent of individuals nationwide reported they had been offered online access to their medical record by a healthcare or insurance provider. Among those individuals offered access, 53 per cent of people accessed their record at least once (40).

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Currently, among smartphone and tablet users (who represent approximately 84 per cent of all Americans), 44 per cent reported having a health or wellness app. As APIs become more broadly adopted, the hope is that individuals will be able to direct their medical record information to their preferred apps to help them better manage their health and healthcare. A direct example of this is that recently Apple partnered with several hospital networks to allow patients to access their health data on the Health Kit app on iPhones using their portal logins and HL7® FHIR®.
3.2.14 UNITED KINGDOM

The digital health programme is being progressed through a portfolio of program delivery aligned to the overall business strategy of the National Health Service (NHS). This strategic direction has been outlined in the NHS Five Year Forward View (44).

The digital health programme is aligned to the key themes underpinning the service transformation outlined in the NHS Five Year Forward View, which include: empower the person; support the clinician; integrate services; manage the system effectively; and create the future.

The digital programs therefore cover a range of areas – from enabling citizen facing services, such as the ability for patients to transact online through the NHS app; the digitisation of hospitals, the underpinning improvement to cyber resilience across the service, through to the delivery of interoperable care records through the Local Health and Care Records program.

Consequently, the portfolio has specific programs focused on interoperability such as Integrating Care Locally which includes the delivery of national capabilities and national standards and the Local Health and Care Records program on the delivery of interoperable care records to enable joined-up care and improved local planning. At the same time, the use of interoperability standards is a key enabler in the delivery of programs across the portfolio – such as the interoperability standards to connect with Personal Health Records (PHRs), and the interoperability standards to expose information from provider systems. Across the portfolio, the national Chief Clinical Information Officer (CCIO) has also outlined the interoperability “CCIO 7” which is a set of priorities that underpin the portfolio. These are:

- Sharing of structured basic observations;
- Sharing of structured dates and schedules;
- Sharing of structured basic pathology information;
- Sharing of medications that are machine readable and interoperable;
- Use of the NHS Number at the point of care;
- The use of a consistent set of terminology and diagnostic codes (SNOMED CT and dm+d); and
- The use of a consistent staff identifier within any information exchange.

Local organisations are responsible for the provision of electronic systems within hospitals and other care settings. As part of these procurements, there are several standards and pieces of functionality that are required. Some of these are legal requirements such as the use of the NHS Number, some are contractual requirements as published through the NHS Standard Contract, some are published policy, and some are recommendations.

NHS England published a “Starter Output Based Specification” document in 2016 which specified a range of standards and services which organisations should ensure are included as part of their procurements.
Within England, the new Local Health and Care Records Exemplars (LHCRE) program has recently been announced. This program is seeking to establish the locally led delivery of interoperable normalised longitudinal health and care records. The LHCREs will be an interconnected set of longitudinal care records facilitated through the use of nationally published standards and supported through connecting national components (e.g. a record locator). This initiative is a service transformation led initiative driven by the move to Integrated Care Systems of which the longitudinal care record will provide a joined-up view of care and data in a de-identified form to inform and improve local planning. The first five of these LHCREs have been announced and cover more than 40 per cent of the population with subsequent waves of Local Health and Care Records to be announced that would use the blueprints from these exemplars to enable national coverage.

These exemplars will implement the capabilities to create an interoperability platform that can enable an ecosystem of apps to use the data from the normalised longitudinal care record.

Within some national services, such as the Summary Care Record, there is implied consent applied to the upload of basic records with explicit consent to add in additional information and consent to view. Patients may, through their GP, dissent from this information being sent to the national service.

In line with the UK Department of Health and Social Care policy regarding opt out of identifiable data being shared for purposes beyond direct care, a National Data Opt-Out Programme was established which is currently in private beta for a national system (web and app-based) to allow patients to express their consent preferences.

Health data 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. Examples include:

- Patient identification – between organisations and in interactions with national services;
- Transfers of care – national standards exist for acute, Accident & Emergency and mental health eDischarges and letters from outpatient clinics;
- Record level transfers of information between care settings;
- Imaging; and
- Pathology.

Note that the above 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:

- **HL7® v2.x** – extensive local use;
- **HL7® v3** – use for existing national components such as GP Summary, Personal Demographic Service etc.;
- **HL7® FHIR®** – for newer specifications (note that the current interoperability policy specifies FHIR® as the default methodology for use; any requests which do not use FHIR® must be justified to the business interoperability design authority);
- **Bespoke XML** – use for several secondary uses collections;
- **READ Codes** – previously used terminology for general practice which has been deprecated but is still present in records;
- **SNOMED CT** – the primary clinical terminology;
- **dm+d (dictionary of medicines and devices)** – the primary national drug terminology;
- **ICD-10** – used across secondary uses collections and within some records;
- **OPCS 4** – classification of procedure codes developed by the UK used across secondary uses collections and within some records;
- **ICD-11** – the UK is participating in the ICD-11 field trials as a WHO-FIC release centre;
- **Transport standards** – various standards including W3C (SOAP et al.), ebXML (OASIS), HTTP, TLS, SMTP, FHIR® RESTful APIs;
- **DICOM** – international imaging standard; and
- **IHE** – various IHE standards are deployed by local organisations and regional structures though there is no national implementation.

FHIR® is the strategic direction for future standards development.

The drive for interoperability in the UK is to move away from this being a technical concept solely about standards but, rather, to be driven by the move to integrated care systems which ensure that interoperability is driven as part of this service change and not separate to it.

Furthermore, there is a strong drive to expose Open APIs from health and care systems (based on FHIR®) to establish ecosystems of apps that can use the data exposed and through SMART on FHIR® containers to enable simplified access to this information.
3.2.15 URUGUAY

The Government of Uruguay, with the financial support of the Inter-American Development Bank (IDB), is developing the eHealth initiative “Programa Salud.uy” with the purpose of strengthening the National Integrated Health System (SNIS), supporting the healthcare system through the use of ICT, and creating tools that contribute to improving the access of citizens to quality health services throughout the country. It also seeks to assist health providers to deliver healthcare that is integrated, efficient and patient-centred.

The National Electronic Health Record (HCEN) is one of the main components of the program, offering national interoperability. Work is underway to add digital prescriptions.

According to Uruguayan law, custody of a patient’s clinical information is the responsibility of their health provider, although there is centralised ICT infrastructure that supports federated access to a patient’s clinical documents in specific healthcare scenarios.

The centralised health platform includes components such as the national Master Patient Index (MPI) and a registry of clinical documents according to the IHE XDS profile.

All citizens are included in the HCEN system, although they are allowed to opt out. A project is currently under development aimed at giving patients greater ability to determine who can access their clinical data.

The health information exchange model in Uruguay is based on the IHE XDS profile exchange model, where there is a trust domain that is given by the SNIS with document repositories in each health provider. Clinical documents exchanged are based on the HL7® v3 CDA® R2 standard, with strong use of clinical terminologies such as SNOMED, LOINC and WHO classifications.

The primary purpose of health data exchange is continuity of care, allowing access to the patient’s medical history, to support better decision-making by the healthcare professionals, and a better quality of healthcare.

The exchange of information is currently based on CDA® documents, using the IHE XDS.b profile. Concept tests are currently being undertaken using HL7® FHIR®.
The following standards are used:

- IHE profiles: XDS.b, PIX/PDQ, ATNA, CT, BPPC;
- IHE profiles in concept tests or pilots: XDS.i, APPC, MDH;
- Clinical terminologies used: SNOMED CT, LOINC, CIE10, CIE9MC, CIAP2;
- Medicines: National dictionary modelled on SNOMED CT;
- Clinical documents identification: LOINC Ontology documents and SNOMED CT;
- Messaging: HL7® v2.53 (XML); and
- Clinical information modelling: EN 13606 y CDA® R2 (HL7® v3).

A citizen website is under development, where patients will be able to access their clinical information. This will allow patients to set access controls and determine which health providers can access their information and in what situation.
4 DISCUSSION

4.1 KEY FINDINGS: COMMON THEMES

In reviewing the survey responses of participating countries and territories, it is evident that countries are at different points in their journey towards successful interoperability outcomes.

However, while this is the case, it is also apparent that the majority of countries face the same fundamental interoperability challenges, albeit addressing them in different ways through the use of a large number of different standards.

The following common themes were found:

- All 15 countries and territories use internationally recognised standards throughout their digital health systems;
- Semantic/code system standards ICD-10, LOINC®, and SNOMED CT® were adopted almost unanimously among the countries and territories that responded to the survey;
- HL7® standards and IHE profiles were most used to meet interoperability use cases;
- Fourteen of the 15 responding countries and territories provided an option for the patient to provide consent for the capture, use, or sharing of their digital health information;
- Patients are involved with their own health data, beyond consent processes, in thirteen of the 15 surveyed countries and territories; and
- Cost-effective and sustainable creation of national Health Information Exchange is essential and there is an opportunity for global harmonization and alignment through standards bodies such as IHE and HL7, which are used internationally; and
- FHIR® is rapidly emerging in many countries and territories as a next-generation interoperability standard.

The following were the most common uses for health data exchange:

- Patient identification;
- Care planning and transition/continuity of care;
- Sharing of electronic health record (EHR) data;
- Electronic prescribing;
- Sharing of imaging results;
- Reporting of laboratory results; and
- Public health registries and reporting.
4.2 KEY FINDINGS: FURTHER INSIGHTS

Further to the common themes across the survey responses, a number of additional insights can be noted. These insights are derived from survey responses, discussions within the Interoperability work stream and additional research into work taking place in participating countries.

Key further insights include:

**Interoperability must become part of healthcare, not an adjunct to it**

As stated in different ways in multiple survey responses, the ultimate measure of success for interoperability will be when its outcomes are considered integral to the delivery of digitally inclusive, safe, high-quality healthcare, and not a separate branch of practice.

**Many key standards in use are international, with strong participation from GDHP countries**

The majority of GDHP countries are making use of a number of international standards, many of which benefit from significant international input.

For example, HL7® International Working Group meetings are regularly attended by over two-thirds of GDHP interoperability survey respondents, ensuring that HL7® standards such as v2, v3, CDA® and FHIR® all benefit from international participation and the representation of requirements from a diverse set of countries. Similarly, IHE International, SNOMED International and ISO all benefit from strong international participation.

The consequence of the high degree of participation in international standards development is that a solid platform exists for driving greater collaboration between GDHP countries in addressing interoperability challenges.

**Many countries are working on the same interoperability problems**

It is clear from the survey responses that many GDHP countries are working on the same, or similar, challenges when it comes to interoperability. In many cases these problems are being approached in a different order, but fundamentally many of these interoperability challenges are structurally similar, albeit with the need for local terminology in each instance.

There is a significant opportunity for GDHP countries to collaborate in addressing complex interoperability problems, sharing expertise, improving the quality of standards and specifications, driving international consistency and reducing duplication of effort.
There is significant variability in choice of standards to solve specific interoperability problems

In addressing interoperability challenges, it is evident that countries are often using different standards to achieve similar outcomes.

While these choices remain the prerogative of individual countries, there are often many standards from which to choose, resulting in countries solving the same interoperability problems using different standards. Although there can be many legitimate reasons for this, it can also result in duplication of effort, making it harder to collaborate between countries.

In addition to this, international health IT vendors are presented with multiple, often competing, requirements for interoperability, resulting in slower time to market for the vendor. A more unified approach to international interoperability requirements could result in better outcomes for all parties.

Standards profiling organizations, such as IHE and PCHA/Continua as well as “Gemini” the Joint Initiative between HL7 and IHE focused FHIR, can help drive global harmonization forward by composing international standards according to best-practice. Greater availability of open, non-proprietary standards can enhance market competition and support new innovative options for consumers. Multiple GDHP countries have made use of this profiling and witnessed benefits in terms of cost-efficiency and sustainability.

One of the areas of greatest variability is the approach to standards used for the interoperability of medications information, including medication lists, medication history and medication administration records. The GDHP Interoperability work stream should give consideration to the potential benefits of international collaboration in this area.

There are diverse approaches to the complex issue of patient consent

Responses to the GDHP current interoperability landscape survey show that there are a range of approaches to patient consent to data storage and sharing:

- Some countries have a highly federated approach, with patient data stored with healthcare provider organisations and patient consent for sharing managed at this level;
- Others have national EHRs which require patients to opt in, managing consent at a national level;
- Other countries have moved to an opt-out model where, once a record has been created, standing consent for storing and sharing data is assumed as implied by the record’s existence; and
- Some countries with national EHRs have created granular access controls to allow patients to choose which records (or documents) remain private or require codes for access.

Patient identification is a key prerequisite for interoperability

There is a clear consensus among GDHP participants that the ability to identify patients correctly is a critical prerequisite to safe and efficient interoperability.
Although some countries have national identifiers, and others rely on the ability to federate regional and healthcare organisation-specific identifiers, the ability to identify patients confidently is a foundational element of successful interoperability.

**Clinical terminology is key to interoperability with “shared meaning” (semantic interoperability)**

The need to code structured data using clinical terminologies, ontologies and vocabularies is another critical component of interoperability.

Although clinical informatics standards provide a way to structure data that can be used to imply meaning, clinical terminologies provide a mechanism for expressing a richer set of concepts with pre-agreed meaning.

While many countries, quite validly, have their own local terminologies for domains such as medications, there appears to be a growing move towards SNOMED CT, LOINC and ICD as nationally standard clinical terminologies.

**FHIR® is seeing rapid adoption**

Survey responses show that many GDHP countries are rapidly adopting FHIR® to address a range of interoperability challenges.

Although there is no one silver bullet for all interoperability challenges, the significant market momentum of FHIR®, combined with a high degree of vendor adoption (through initiatives such as the Argonaut Project\textsuperscript{10} based in US (45)), its structured approach to profiles and extensions, and growing national adoption, makes FHIR® a promising candidate standard for a number of future interoperability challenges.

However, since many countries are working on the same interoperability problems, the uptake of this new standard implies the same need for global collaboration, harmonization and profiling according to best-practice to achieve maximum cost-efficiency and sustainability in the long term.

\textsuperscript{10} http://argonautwiki.hl7.org/index.php?title=Main_Page
4.3 RECOMMENDED NEXT STEPS

This report outlines the respective national approaches to interoperability within a number of participating GDHP countries.

While there is a diversity of focus, priorities and progress, there are clearly many common (or highly similar) interoperability challenges, and all countries would clearly benefit from increased knowledge sharing and collaboration.

To that end, it is proposed that the following issues be tabled for discussion at the next GDHP meeting in India:

- **How can participants share lessons learned and reduce duplicated effort?**
  With many countries working on similar interoperability challenges, how can countries who are further ahead in specific areas share the progress that they have made, and the lessons that they have learned?

- **How can participants collaborate to become better global buyers?**
  How can countries work together to present, where appropriate, a more unified set of international requirements to Health IT vendors, with the aim of driving down cost and decreasing time to market for Health IT solutions.

- **How should standards alignment be addressed globally?**

- **How can nations support, foster and cooperate with international standards development organizations?**

- **What one thing can participants collaborate on that would make a difference?**
  Is there an initial area where GDHP participants could work together to deliver value through increased collaboration and standardisation of approach? Would a globally harmonised and aligned FHIR®-based representation of medication lists be a good candidate for such collaboration?

Finally, GDHP countries are strongly encouraged to actively participate in the Interoperability work stream moving forward, as greater diversity of input will result in higher quality work that is mindful of different country and regional drivers for interoperability and the need to strive for digital inclusion as a human right.

Countries are also encouraged to ensure their participation in relevant international standards bodies such as HL7® International (46), SNOMED International (47), IHE International (39), ISO (48) and others as appropriate.
### APPENDIX A | LIST OF GDHP PARTICIPANT RESPONDENTS

<table>
<thead>
<tr>
<th>GDHP participant country</th>
<th>Name of representative who responded</th>
<th>Organisation</th>
</tr>
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<tbody>
<tr>
<td>Argentina</td>
<td>Dr Alejandro Lopez Osornio</td>
<td>Ministry of Health Systems</td>
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<tr>
<td></td>
<td>Dr Daniel Rizzato</td>
<td>Director, Health Software Development</td>
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<tr>
<td>Australia</td>
<td>Brad McCulloch</td>
<td>Australian Digital Health Agency</td>
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<tr>
<td></td>
<td></td>
<td>Program Manager Interoperability</td>
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<tr>
<td>Austria</td>
<td>Jürgen Brandstätter</td>
<td>Ministry of Labour, Social Affairs, Health and Consumer Protection / ELGA GmbH</td>
</tr>
<tr>
<td></td>
<td>Martin Hurch</td>
<td>Head of Architecture and Operations, ELGA GmbH</td>
</tr>
<tr>
<td>Canada</td>
<td>Lynne Zucker</td>
<td>Canada Health Infoway</td>
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<td></td>
<td></td>
<td>Executive VP, ACCESS Health</td>
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<tr>
<td>Hong Kong</td>
<td>Ian CHIN</td>
<td>Hong Kong Hospital Authority (HA)</td>
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<tr>
<td></td>
<td>N. T. CHEUNG</td>
<td>Head (Information Technology / Health Informatics); Consultant (Electronic Health Record)</td>
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<tr>
<td></td>
<td>Clara CHEUNG</td>
<td>Chief System Manager</td>
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<td></td>
<td>H. L. HUI</td>
<td>Chief System Manager</td>
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<tr>
<td></td>
<td>Clement CHEUNG, Senior Health Informatician</td>
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<td></td>
<td>Vicky FUNG</td>
<td>Senior Health Informatician</td>
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<td>Michael CHEUNG</td>
<td>System Manager</td>
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<td></td>
<td>Leo LEE</td>
<td>System Manager</td>
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<tr>
<td>India</td>
<td>S.C Rajeev</td>
<td>Ministry of Health and Family Welfare (MoHFW)</td>
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<td></td>
<td>Ankit Tripathi</td>
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<tr>
<td>Italy</td>
<td>Andrea Urbani</td>
<td>National Center for Health Technology Assessment, Italian National Institute for Health</td>
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<td></td>
<td>Walter Ricciardi</td>
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<td>Japan</td>
<td>Mr. Soichiro Sasago, Ms. Haruna Ikami, Ms. Seiza Miyazaki, Mr. Kenshin Shimizu</td>
<td>Ministry of Health, Labour and Welfare</td>
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<td></td>
<td>Dr. Kazuo Minamikawa</td>
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<td>Alastair Kenworthy</td>
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<td>Saudi Arabia</td>
<td>Ahmed Balkhair</td>
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<td></td>
<td>Tarek Ahmed Hakeem</td>
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<td>Emelie Gross</td>
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<td>United States</td>
<td>Donald Rucker</td>
<td>U.S. Department of Health and Human Services</td>
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<td>National Coordinator for Health Information Technology</td>
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<td>Director, Office of Technology</td>
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<td></td>
<td>Teresa Zayas Cabán</td>
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<td>Inderjit Singh</td>
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<td></td>
<td>Head of Architecture and Cyber Security</td>
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<tr>
<td></td>
<td>Ian Townend</td>
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<tr>
<td></td>
<td>Lead Architect</td>
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<tr>
<td></td>
<td>Salud.uy Program Manager, Executive Director</td>
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REFERENCES


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### ACRONYMS AND ABBREVIATIONS

<table>
<thead>
<tr>
<th>Acronym/Abbreviation</th>
<th>Meaning</th>
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<tr>
<td>API</td>
<td>application programming interface</td>
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<tr>
<td>app</td>
<td>mobile application</td>
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<td>CCM</td>
<td>Chronic Care Model</td>
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<td>DICOM</td>
<td>Digital Imaging and Communications in Medicine</td>
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<td>dm+d</td>
<td>dictionary of medicines and devices</td>
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<td>FHIR®</td>
<td>Fast Healthcare Interoperability Resources</td>
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<td>Global Digital Health Partnership</td>
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<td>GDPR</td>
<td>General Data Protection Regulation (EU)</td>
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<td>IHE</td>
<td>Integrating the Healthcare Enterprise</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>LOINC</td>
<td>Logical Observation Identifiers, Names and Codes</td>
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<td>MHD</td>
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<td>patient-generated health data</td>
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<td>REST</td>
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<td>SNOMED CT</td>
<td>Systematized Nomenclature of Medicine Clinical Terms</td>
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<td>SOAP</td>
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<td>SS-MIX2</td>
<td>Standardized Structured Medical record Information eXchange</td>
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<td>XCA</td>
<td>IHE Cross-Community Access</td>
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<td>XDR</td>
<td>IHE Cross-Enterprise Document Reliable Exchange</td>
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<td>IHE Cross-Enterprise Document Sharing</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WHO-FIC</td>
<td>WHO Family of International Classifications</td>
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