



Department
of Health &
Social Care

G7 Open standards and Interoperability

Final Report

Published 30 December 2021

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Purpose of this report

This report reiterates the commitment of the G7 countries to facilitating and promoting the use of open standards for international health data to encourage the widest possible adoption of standards and greater interoperability.

Summary

The implementation of standards in terms of cross-border interoperability varies widely across the G7 countries. This is largely due to the way systems have developed over the years and how technology was implemented.

In some countries, regions have developed local protocols. In others, interactions between public and private healthcare use variable, bespoke systems with little standardisation. In the UK the four devolved administrations have responsibility for health and care, resulting in distinct borders when it comes to implementation of health information standards.

Efforts are being made to address these concerns at the country, European, and international level, and standards organisations are increasingly involved in bringing these efforts into alignment. This G7 commitment offers the opportunity to accelerate these efforts.

The following principles were agreed:

- the G7-IPS will conform to open and international standards wherever possible
- standards should be open in terms of both availability and implementation and largely free of charge, allowing for as wide a choice of approach as possible and frequent updates where necessary
- standards should be compatible with open-source development and permissive licensing
- we should support mature and reusable standards that are already deployed across the G7 countries and conform to national legislation or policy, wherever possible
- open standards should support easy patient access and clinical safety, through a wide variety of interfaces and with clarity and consistency
- these standards should refer to data, data exchange, programming code, security, document formats and user interfaces

Some G7 countries are already pursuing an aggressive strategy for implementation of standards and expect to see results within two years. Others have made broad commitments for an integrated health system within the next eight years, some are starting their discovery phase. The UK has recently begun implementation of a strategy to allow information flow between its own borders and find itself roughly in the middle of the standards implementation journey.

G7 commitment on digital health

The health ministers of the G7 countries met on 3-4 June in Oxford and signed a communiqué agreeing to collaborate on four health track themes. Ministers made the following commitments on digital health:

Recognition of the importance of digital health solutions in transforming healthcare and of the need for appropriate data governance, system security, regulatory, and data protection standards in order to benefit from advances in digital health.

Commitment to working towards adopting a standardised minimum health dataset for patients' health information, including through the International Patient Summary (IPS) standard; developing internationally shared principles for enabling patient access to health data and promoting the use of open standards for health data.

Recognition of the need for multilateral collaboration on a standards-based, minimum data set for COVID-19 testing and vaccination verification and commitment to work within existing WHO processes to develop this and to work as G7 countries towards a process of mutual acceptance of COVID-19 certificates.

Recognition that governance of artificial intelligence (AI) systems in the health sector must be strengthened in order to keep pace with technology development.

Commitment to working together to define and develop a shared understanding of phases for how we clinically evaluate health AI algorithms and develop and share best practices for benchmarking the suitability of a health AI algorithm developed in one G7 country for potential deployment in another.

Open standards and interoperability

The G7 health ministers' declaration commits to facilitating and promoting the use of open standards for international health data to encourage the widest possible adoption of standards and greater interoperability, specifically within an IPS context.

The following paragraphs show the full wording of the [commitment](#):

Interoperability

We recognise the importance of digital health solutions in transforming healthcare including but not limited to in response to pandemics. In order to derive maximum benefit from advances in digital health, we need to have data governance, system security, privacy, regulatory and data protection standards in place according to national and

regional contexts. This includes ensuring that digital health solutions are inclusive, comprehensive and equitable. The ability for digital healthcare systems to work together seamlessly using common and open standards is critical to the safe, effective and efficient use of technology in health and care. At present, there is significant variability within and across nations with respect to how computable health data is represented and used for healthcare and in the standards used for patients' health data.

Open standards

We support countries and territories in developing their own digital health policy in line with WHO guidance towards comprehensive digital health systems that protect privacy and equity of health care access. We support the development of and the building upon existing open health data standards, open-source software tools and related infrastructure so that international investments made remain accessible and adaptable to changing requirements.

International patient summary

We commit to work towards adopting a standardised minimum health dataset for patients' health information, including through the International Patient Summary (IPS) standard, with the shared objectives of facilitating health interoperability within and between countries, developing internationally shared principles for enabling patient access to health data, based on the principle of informed explicit consent or patient permission and in keeping with countries' and regional existing legislative frameworks; and facilitating and promoting the use of open standards for international health data to encourage the widest possible adoption of standards and greater interoperability. To achieve this goal, we will work with the Global Digital Health Partnership (GDHP) as they are already advancing IPS efforts.

Current position

The G7 countries vary in their implementation of and commitment to cross-border interoperability. No small part of this is due to difficulties around standards.

Some countries, such as Canada and the UK, have devolved healthcare to their local jurisdictions, resulting in the development of local protocols and distinct borders. In other countries, where interactions are predominantly between public and private healthcare providers, systems are variable with little standardisation.

Nonetheless, efforts are being made to address these concerns at the country, European, and international levels, and organisations are increasingly bringing these efforts into alignment.

Principles

The G7 standards and interoperability working group provided the opportunity to align to open and common standards and accelerate interoperability efforts. As such, we agreed the following principles:

1. the IPS created through this working group should conform to open and international standards wherever possible
2. these standards should be open in terms of both availability and implementation and largely free of charge, allowing for as wide a choice of approach as possible and frequent updates where necessary
3. standards should be compatible with open source development and permissive licensing
4. where possible we should support mature and reusable standards that are already deployed across the G7 countries and conform to national legislation or policy
5. open standards should support patient access, actively encouraging ease of access through a wide variety of interfaces and clinical safety with clarity and consistency
6. these standards should refer to data, data exchange, programming code, security, document formats and user interfaces

Appendix A describes the status, plans and ambitions for achieving these principles for each G7 country.

Implementing open standards - putting principles into practice

G7 Countries are already working towards meeting these principles (see [Appendix A](#)) with each country at different stages of implementation.

Some G7 countries are already pursuing an aggressive strategy for implementation of standards and expect to see results within two years. Others have made broad commitments for an integrated health system within the next eight years and some are just starting their discovery phase.

European Union

Several European countries face this challenge and are now considering how best to implement EU level ambitions. Where those ambitions overlap with the principles above and the open standards committed to in the declaration, the G7 should aim to support that process and provide support for equivalent challenges elsewhere.

Recommendation

The G7 should work together to review the current and planned use of standards (WHO ICD and ATC, SNOMED CT, HL7 CDA and FHIR, IHE etc.) promoted through organisations like the Global Digital Health Partnership and eHealth Network, and ensure that these align with our principles.

Current position

To gauge where each country is regarding alignment to the principles and understand what barriers they face and their future plans, an open standards survey was completed, which asked the following questions.

1. Which (relevant) open standards are currently used in your country's health system?
2. What are open standards in use for, what areas are covered?
3. Who sets standards in your country? Who is responsible for their implementation?
4. Is there any centralised repository or portal for health standards?
5. What barriers, if any, have you encountered?

6. How have you overcome any barriers to the implementation of open standards?
7. What learning / advice would you like to share with the group?

Countries' detailed feedback is in [Appendix A](#).

Summary of findings from the open standards survey

There were some common themes which emerged from the survey.

Collective working and support

There was a strong push for interoperability, open standards, and IPS implementation across the EU during the pandemic.

This resulted in many international and national bodies working together in new and highly effective ways, which has brought additional benefits such as the purchasing of community licences to progress implementation across federated states.

Bodies have been set up in some member states to coordinate across multiple healthcare organisations.

Some common standards have been agreed even when G7 members have a large number of internal borders, thanks to substantial engagement efforts with public and private stakeholders.

Consistent testing tools and validators are starting to emerge.

Interoperability strategies

Canada, the UK and the EU are developing interoperability strategies.

Support and recognition of expert organisations

Within the G7 there is wide-scale support for standards organisations, especially [GDHP](#), [ISO](#), the [eHealth Network](#), [SNOMED International](#), [IHE](#) and [HL7](#).

Examples of blockers

Political:

- lack of centralised tracking of national standards until the last few years

- lack of a cohesive national-scale digital health system or electronic health record, with data missing at point of care
- uncertainty around national regulation or legislation and multiple forms of relevant regulations of varying ages
- internal borders, whether due to federation, devolution, or market forces
- international licensing standards compatibility (with SNOMED CT, less so FHIR)

Funding and resources:

- resource costs, direct or indirect, and economic barriers
- lack of maintenance and support structures and uncertainty around the relevant costs
- variable levels of support for national standards in general

Knowledge:

- lack of knowledge regarding implementation or advanced functions of more complex standards for both implementers and vendors

Infrastructure:

- potential for high impact on pre-existing workflows
- inconsistent approaches to procuring and implementing technology for healthcare
- narrowly focussed (and potentially incompatible) vendor-specific solutions and proprietary/unique data formats without scope to spread and scale
- inconsistent maturity of data quality and exchange
- lack of consistent patient ID
- broad uptake of record exchange by pdf

Plans for the future

Canada is planning for a “fully integrated and continuously optimised health data ecosystem” by 2030.

The eHealth Network of the EU (working since 2019) has implemented a subgroup on semantics to elaborate and implement a semantic strategy for the EU.

France is aiming towards convergent interoperability across national, EU and international scales, with a health strategy that is being implemented over the next 2 years to achieve full national interoperability. Phase 1 will put in place technical pillars in health institutions and providers. Phase 2 will upgrade systems to EU and international interoperability specifications.

Germany has implemented legislation to enable a national effort towards a standardised electronic health record for all citizens embedded in a national interoperability framework.

Italy plans to make its 21 regional services interoperable through open standards adoption, applying the principles of EU interoperability nationally.

Japan is considering the adoption of HL7 FHIR.

The UK will be releasing a Standards and Interoperability Strategy in 2022.

The US is actively supporting work under the GDHP.

G7 minimum set of open standards

International standards applicable to IPS

A minimum / non-exhaustive Patient Summary Dataset for Electronic Exchange is being discussed by the [eHealth Network](#), while a Global Master Standards Guide has been proposed by GDHP participants. While both organisations continue their work, a minimum set of open standards for this project is still necessary.

At present, that list (included in this group’s IPS proof of concept) contains the following standards:

- [ISO 27269:2021](#) | Health informatics - International Patient Summary
- [HL7-FHIR R4](#) International Patient Summary

- [ISO 9241-210](#) | Ergonomics of human-system interaction - Part 210: Human-centred design for interactive system

Other international standards

Further international standards to consider then include:

- [HL7 v2/v3/CDA](#)
- WHO International Classification for Diseases 9th/10th/11th Revisions ([ICD](#))
- WHO [International Nonproprietary Names](#) for pharmaceutical substances ([INN](#))
- [CEN TS 17288](#) | The International Patient Summary
- SNOMED CT Global Patient Set ([GPS](#))
- WHO - International Classification of Health Interventions ([ICHI](#)).
- ISO Identification of Medicinal Products ([IDMP](#))
- EMA Substances, Products, Organisations, Referentials ([SPOR](#))
- Orphanet nomenclature of rare diseases ([ORPHAcodes](#))
- European Medical Device Nomenclature ([EMDN](#))
- European Directorate for the quality of Medicines and Healthcare ([EDQM](#))
- WHO - International Classification of Functioning, Disability and Health ([ICF](#))
- WHO - Anatomical Therapeutic Chemical Classification System ([ATC](#))
- EDQM Unified Code for Units of Measure ([UCUM](#))
- Logical Observation Identifiers Names and Codes ([LOINC](#))
- Nomenclature for Properties and Units ([NPU](#))
- Digital Imaging and Communications in Medicine ([DICOM](#))
- Integrating the Healthcare Enterprise ([IHE](#))
- Medical Dictionary for Regulatory Activities ([MedDRA](#))

Meeting future requirements

Standards adoption should support future requirements where possible, including:

- an agreed scheme of preferred code systems for international transfer that support gradual convergence
- alternate options for mismatches in mapped concepts
- transcoding into relevant languages at point of use
- identification for each citizen suitable for healthcare purposes
- joint licensing activities

Roadmap, priorities and next steps

To reduce or remove barriers to adoption of these standards, a coordinated approach across the G7 countries is required. This will support the implementation of IPS and have broader advantages for national and international healthcare.

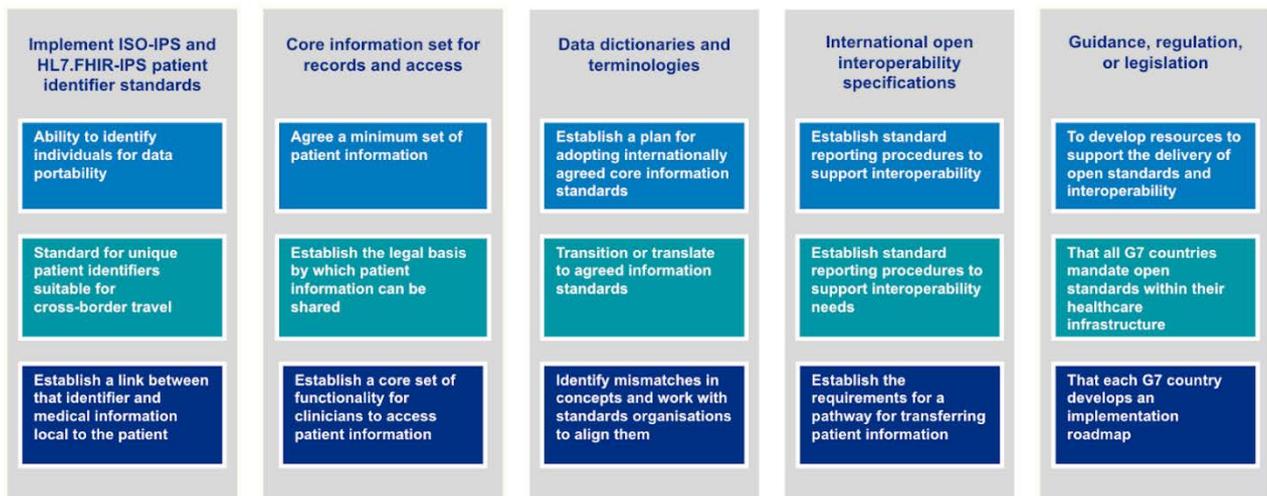
The open standards and interoperability roadmap consists of themes and elements that will assist each G7 country to work towards adopting open standards throughout their healthcare infrastructure. It enables each G7 country to work at their own pace and supports learning and sharing of ideas and processes.

We propose that the G7 countries adopt and implement open standards with an approach built from the following elements and that they continue to collaborate in this area, sharing and learning from each other. These next steps cover diverse areas, clinical, technical, legal and policy. Stakeholders in each of these areas must be actively engaged in the adoption of open standards required to implement a functioning IPS, and in the development of national and international engagement strategies.

Communities (clinical, technical, patient, provider) must be empowered to collaborate and build consensus on the adoption of standards and specifications that are right for each of the applications (diseases, substances, medical devices, etc.) listed above.

Moving from local code systems to internationally recognised standards that facilitate consistent exchange of data and information, will take time and effort. Ensuring that G7 countries have identified a clearly responsible organisation for each application will help keep stakeholders committed and engaged. Whether they are the bodies, portals and initiatives identified in Appendix A or others, national organisations and programmes (such as the [USCDI](#) and [SVAP](#)) can help promote, coordinate and coalesce these efforts.

Throughout this process, sustainability must be kept in mind, both in terms of environmental governance and the maintenance of a long-term programme of work. As adoption and implementation are achieved, new generations of standard and specification are likely to evolve. This is not just an opportunity to agree how standards are adopted and used now but how that process can work into the future.



Implement ISO-IPS and HL7.FHIR-IPS patient identifier standards

Objective

The ability to consistently identify individuals and their data, whether through Patient ID or a map of pre-existing identifiers (e.g. insurance policy information).

Standardisation

Create a standard to provide an individual with a unique identifier suitable for cross-border travel, ensuring that this standard can also be used internationally.

Use

Establish a minimum viable way to use that identifier to access the patient's medical information (in their home system).

Initially this could be something as simple as a contact phone number, and access to receipts of prescription medicines.

Example format

For the US, Canada or Japan this might be a

- code for country
- letter code for state/province/territory/prefecture

- letter code for insurance provider
- policy number rounded out with 0s to a standard length

Use case

The G7-IPS is reliant on unique identifiers for each patient.

Core information set for patient records and access

Objective

To identify the minimum set of patient information with the most use for care away from home, and to establish that set as a national and international standard (i.e. the IPS).

Standardisation

Establish the legal basis by which this information can be shared, complete with appropriate conditions and caveats, inclusive of consented and non-consented uses.

Use

Establish a core set of functionality for healthcare professionals and patients to access that information.

Agreed standard

The ISO IPS data structure and definitions is the agreed dataset and adopted standard for the [G7 roadmap to adopt the IPS](#).

Use case

Some uses and kinds of access (e.g. research purposes) may be appropriate at the national level, but not the international level. These cases should be broadly consistent across countries.

Data dictionaries and terminology servers

Objective

Establish a plan for adopting internationally agreed standards for the minimum information set, including joint licensing options, national and international reporting, diagnosis and prescribing requirements.

Standardisation

Standards are agreed and national organisations move to those standards or adopt a process to translate between their internal coding and those standards.

Use

Identify mismatches in concepts and work with standards organisations to align them or provide alternatives.

Use case

The EU will co-fund SNOMED CT licences for a given number of years to facilitate SNOMED CT adoption by European countries. This supports the sharing of information in the MyHealth@EU initiative.

International open interoperability specifications

Objective

Adopt internationally agreed open interoperability specifications for referral and transition of care.

Standardisation

Establish standard reporting procedures to support interoperability needs, including health professional validation, and processes to ensure coherent records from multiple kinds of input.

Requirement

Establish the requirements for a logistical pathway by which patient information can be referenced outside its system of origin with consideration given to legal context.

Use case

This could be how data is shared, for example, for IPS it might initially be a printed record, or a QR code held by the patient in print or digitally.

It will also cover how information is generated, transferred between systems, and how it's stored (if it is).

Guidance, regulation, or legislation to help ensure interoperability among providers and services.

Objective

To develop resources to support the delivery of open standards and interoperability:

- consistent patient identifier
- core information set for patient records and access
- data dictionaries and terminologies
- international open interoperability specifications

Standardisation

That all G7 countries mandate open standards within their healthcare infrastructure.

Requirement

That each G7 country develops an implementation roadmap.

Appendix A: Open standards survey

Question 1:	Which relevant open standards are currently used in your country's health system?
Canada	<p>HL7 standards: FHIR, CDA, v2 and v3 SNOMED CT-CA, LOINC and the pan-Canadian constraint of LOINC known as the pan-Canadian LOINC Observation Code Database (pCLOCD) for laboratory LOINC document ontology HL7 vocabularies (code systems and value sets) Infoway owned and maintained code systems for provide type and expertise (SCPTYPE and SCPQUAL) UCUM DICOM, DICOM-SR ICD-9 (billing) ICD-10-CA/CCI ICD-O-3 ISO 3166-1, 3166-2 codes for countries and their subdivision ISO 639-3 Language codes IHE International profiles: PIX, PDQ, XDS, XDS-I.b, CT, ATNA, MHD MedDRA International Classification for Nursing Practice (ICNP) Canadian Health Outcomes for Better Information and Care (C-HOBIC)</p> <p>Canada has not yet made a formal decision on ICD-11</p>
France	<p>HL7 Standards: FHIR, CDA* (HL7 V3), HL7-V2* ISO* W3C: web semantic (RDF, OWL, SPARQL), XML, HTTP IHE profiles ICD-10 (WHO), migration planned to ICD-11 (WHO) ICPC-2 Loinc* CCAM (French), migration planned to ICHI (WHO) CIS, CIP (ANSM, France), UCD (CIP Club, France), Medicabase* (Medicabase), ATC (WHO) Orpha (Orphanet France), HPO*, Gene ontology ADICAP (France), ICD-O (WHO) Migration planned to ICD-11 Cladimed (France), migration planned to EMDN EDQM Standards terms</p>
Germany	<p>There are multiple standards in use. Semantic standards use international code systems as much as possible (SNOMED CT, ICD-0-3, LOINC but some national standards have to be used for now as well (PZN, ASK, OPS, others). Technically the new definitions of the content of the electronic health record rely on HL7 FHIR, but some other standards are in use as well. For instance, the upcoming instant messaging system will rely on the Matrix-Protocol.</p>

Question 1:	Which relevant open standards are currently used in your country's health system?
Italy	<p>In Italy we use the IHE standard to allow IT systems / infrastructures interoperability and communication.</p> <p>For documents, we are:</p> <ul style="list-style-type: none"> Implementing HL7 CDA v.2 level 1 and level 3; Using international standard ICD-9-CM for clinical data concerning pathologies and procedures; Using WHO ATC for pharmaceuticals; Using LOINC for Lab reports and procedures; Using MEDRA for pharmacovigilance <p>ISO standards, e.g. 3166-1 for Country codes and 639 for Languages.</p>
Japan	<p>There is no specific national standard for now. The Ministry of Health Labour and Welfare (MHLW) is considering this at the moment.</p>
UK	<p>England and Wales: HL7 FHIR, IHE, ICD, SNOMED CT, LOINC, DICOM</p>
USA	<p>FHIR: FHIR R4 is currently used by health insurers providing administrative and health data to members. FHIR R4 is also currently adopted by health providers, with widespread adoption for patient access expected by the end of 2022. Prior versions of FHIR have been used over the past 3-5 years in the United States which include DSTU2 and STU3, although the market is rapidly consolidating on FHIR R4. This trend has largely been driven through adoption of the US Core profiles (previously Argonaut Project) which provides guidance on the data elements and terminologies to be used for communicating the US Core Data for Interoperability (USCDI) in FHIR. The USCDI describes a standardised set of health data elements for nationwide, interoperable health information exchange. The USCDI is updated annually through input from advisory groups and public comment.</p> <p>C-CDA: C-CDA R2.1 is currently widely adopted with billions of clinical documents exchanged annually. C-CDA remains a core component of data exchange both by public and private health information exchanges, of which there are over 100 in the United States. Multiple document types within C-CDA are actively exchanged and are required for adoption in certified health IT products (CCD, Discharge Summary, Referral Note, and Care Plan Document Templates), the vast majority of which have structured data elements in accordance with the USCDI. In addition to C-CDA standard, multiple companion guides have been developed to provide guidance on adoption and implementation among various use cases.</p> <p>CDA: The usage of CDA templates outside C-CDA is partly adopted for specific use cases in the United States. Some electronic case reporting has been utilized by public health (e.g. HL7 Standards Product Brief - HL7 CDA® R2 Implementation Guide: Public Health Case Report) and quality reporting (e.g. HL7 Standards Product Brief - HL7 CDA® R2 Implementation Guidelines), although there remains a strong connection between those standards and C-CDA templates for transmitting data.</p> <p>In addition to the standards highlighted above, multiple other standards are routinely used for the transmission of claims, pharmacy, public health and other data in the United States (e.g. HL7 v2 messages).</p>

Question 2:	Who sets standards?
Canada	<p>Canada Health Infoway and the Canadian Institute for Health Information (CIHI) work closely with provinces and territories, with input from industry, to arrive at a consensus on pan-Canadian standards. Both organisations also manage and maintain various standards.</p> <p>Infoway defines and manages programs in support of provinces and territories to develop and deploy interoperability specifications based on base standards (HL7, LOINC, SNOMED CT, etc). Infoway also supports Canada's participation in IHE, ISO, HL7 international and other SDOs. Infoway convenes, mobilises and funds standard setting efforts in collaboration with multiple stakeholders.</p>
France	<p>ANS (the French e-health agency) promotes the use of open standards in interoperability.</p>
Germany	<p>The semantic definition of the content of the electronic health records is by law in the hands of the organisation of the statutory health physicians (KBV); technical standards are set and profiled by gematik. Semantic standards for cross border exchange are defined by BfArM.</p>
Italy	<p>The Ministry of Health in cooperation with AgiD (Agency for Digital Italy), which is the technical agency of the Presidency of the Council of Ministers, are responsible for the official publication of standards.</p>
Japan	<p>MHLW has been trying to set standards.</p>
UK	<p>England and Wales: standards are set by a combination of NHS departments, the Department of Health and Social Care, Digital Health & Care Wales - Design Authority (in Wales), and a number of independent bodies such as the PRSB.</p>
USA	<p>Standards are developed and published through standards development organisations (SDOs), which are then cited in federal regulations for specific federal programs. The US Department of Health and Human Services is the primary federal agency involved in the selection of standards for federal regulation. States and localities may also reference SDOs in other regulations. The primary SDO cited for FHIR, C-CDA and CDA is Health Level 7 (HL7). For other data standards, other SDOs are cited by federal regulations (e.g. ASC X12 and NCPDP).</p>

Question 3:	Who is responsible for implementing these standards?
Canada	Provinces and territories are primarily responsible for the implementation of standards within their health systems. Generally these are implemented through industry solutions. Infoway also plays a role through national services such as the pan-Canadian e-Prescribing platform (PrescribeIT). Infoway, CIHI and other national organisations provide advice, guidance, tooling and assistance to public and private implementers.
France	ANS (French e-health agency) promotes the use of open standards in interoperability.
Germany	Multiple organisations and private vendors are engaged in the implementation of the standards in diverse software products in healthcare.
Italy	The Ministry of Health, the Ministry of Economy and Finance and each Italian Region for specific competencies / roles.
Japan	Vendors are responsible for implementing standards.
UK	All NHS bodies in England and Wales, as they implement new projects and programmes.
USA	EHR vendors are responsible for certifying technologies which are then implemented by healthcare hospitals and providers. Other health IT technologies using standards are also commonly implemented by health information exchanges, health insurers and other healthcare participants.

Question 4:	Is there a centralised repository or portal for health standards?
Canada	<p>Canada Health Infoway provides a central repository of interoperability standards and specifications reviewed on a bi-annual basis to keep it current and relevant.</p> <p>CIHI and Health Canada also provide access to health standards specific to their mandates via websites and collaboration portals.</p> <p>Several provinces and territories also maintain and provide access to relevant standards and specifications, specific to their health systems. Some are based on pan-Canadian work products, some are specific to individual projects or solutions.</p>
France	<p>ANS has three repositories for health standards:</p> <p>A repository to publish the health standards: CI-SIS (Interoperability Framework for health Information Systems)</p> <p>A repository to publish terminologies using Web Semantic standards Multi-Terminology server: Serveur Multi-Terminologies</p>

Question 4:	Is there a centralised repository or portal for health standards?
	<p>A testing platform for interoperability https://interop.esante.gouv.fr/EVSCClient Espace de tests d'interopérabilité esante.gouv.fr</p> <p>France organises a 'projectathon' each year: a short session of 2 or 4 days where vendors can test the conformity of their solutions to the CI-SIS.</p>
Germany	<p>There is a portal hosted by gematik called vesta, which lists all kinds of standards and especially those relevant for the national infrastructure in healthcare. It will be taken over by a new platform called ina (interoperability navigator in digital health), hugely extended content wise and translated into English in 2022. Code systems are provided through a portal of BfArM.</p>
Italy	<p>The “Portale AgID” which publishes specifications and related documents and decisions.</p>
Japan	<p>There is no centralised repository at the moment.</p>
UK	<p>England and Wales: A list of all current approved national information standards is available, work is underway by NHSX to create a fully featured standards portal. API portals are also available.</p>
USA	<p>There is no mandated fully centralised repository for all health data standards.</p> <p>The US Department of Health and Human, Office of the National Coordinator for Health IT (ONC) hosts a robust website with broad resources for the adoption of standards and health information technology: HealthIT.gov. The ONC has a list of standards specified in their regulations at Standards Version Advancement Process Interoperability Standards Advisory (ISA) and current and potential future standards to be considered at Interoperability Standards Advisory (ISA). A Technical Assistance website for FHIR implementation resources among healthcare providers and insurers has also been developed by the US Department of Health and Human, Centers for Medicare and Medicaid Services (CMS).</p>

Question 5:	What barriers have you encountered?
Canada	<p>Differing health priorities and implementation timelines between the various provinces and territories make harmonisation of interoperability standards more complex.</p> <p>The multiplicity of health systems (across and within provinces and territories) and variability of clinical practices and clinical solutions make semantic harmonisation very challenging.</p> <p>There is a need for harmonisation in legislation and policy to address gaps</p>

Question 5:	What barriers have you encountered?
	<p>and barriers to improve data sharing for individual care, population health and public health.</p> <p>There is a need for a sustainable model for the evolution of standards and continued upgrade of solutions to implement changes in a timely manner.</p> <p>Sustained clinician and patient support and change management is needed.</p>
Germany	Barriers lie mainly in the alignment of legacy standards and in proprietary code systems or standards.
Italy	<p>Standards implementation regarding clinical documents is managed at a local level by the Italian Regions (Italy has 21 regional health systems) who in the past years have developed regional specifications. More recently, Italy has been working to unify regional specifications, in line with the goals of the European Commission.</p> <p>Differences between regional infrastructure backgrounds present barriers to standards harmonisation. However, ATC standard (for pharmaceuticals) and ICD-9-CM are common across all the 21 Regions (this is also due to reimbursement reasons concerning healthcare services).</p>
Japan	One of the issues in Japan regarding standardisation is that there is weak support for connectivity with on premise systems and various medical devices due to vendors' proprietary specifications and unique data storage formats.
UK	England and Wales: It can take a long time for standards to be adopted across the health system in England and Wales, as different local providers have different IT solutions and needs.
USA	<p>Coordination of standards across multiple regulations spanning multiple years, such as quality reporting, public health, patient access and care continuity, remains a challenge. The Office of the National Coordinator for Health IT (ONC) is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information to address these challenges. In addition, heterogeneous data quality among various technologies, as documented in peer-reviewed research (Interoperability Progress and Remaining Data Quality Barriers of Certified Health Information Technologies), remains a barrier to meaningful health information exchange that the ONC and other healthcare participants continue to address.</p>

Question 6:	How have you overcome barriers to implementing open standards?
Canada	There is great cooperation between provinces and territories, Infoway and

Question 6:	How have you overcome barriers to implementing open standards?
	<p>other key stakeholders including the private sector, and a general commitment to open standards.</p> <p>An effective collaborative approach is key to success, bringing together both public and private sector stakeholders. Prioritisation and developing a shared roadmap is also key, through concerted governance.</p> <p>A shared sense of urgency, as seen through the pandemic, has exposed issues but also demonstrated that great progress can be accomplished in a very short time: there is renewed pan-Canadian engagement and this is very exciting.</p>
France	<p>The Digital Republic Bill Etalab</p>
Germany	<p>Through a new legislative framework, which will foster interoperability in healthcare through a coordinated governance mechanism, many barriers could be addressed soon. This legislation became effective in October 2021 and the process of implementation has already started. Its main purpose will be to define among experts and with stakeholders how to address the most pressing barriers to the use of standards in healthcare. Gematik acts as a coordination office for the decision-making and governance. Outcomes and much more will be provided on the web platform ina.</p>
Italy	<p>There is a great cooperation between the Ministry of Health, Agid and Regions to address the issues concerning standards and interoperability. The “Sistema Tessera Sanitaria”, which is the national health registry, the “Fascicolo Sanitario Elettronico” (Electronic Health Records), and the pharmaceuticals procedures (e-prescriptions) are already the same for all the Regions. However, for many other code systems, the Italian Regions can still decide what to use as preferred.</p>
Japan	<p>For the standardisation of electronic medical record information and exchange methods, Japan is considering the use of HL7FHIR, which is based on international data linkage specifications that can respond to technological developments taking into account its usefulness in the medical field.</p>
UK	<p>England and Wales will be looking to release a Standards and Interoperability Strategy next year. Both will look to take advantage of the recent restructuring of the UK healthcare system into Clinical Commissioning Groups responsible for services in their local area.</p>
USA	<p>Arriving at common standards across multiple market participants has been a major accomplishment. Specifically, both healthcare providers and health insurers are using the FHIR R4 profiles developed by US Core, which provide a common basis for accessing health data. We are encouraged with the increasing adoption of FHIR R4 as a common standard for health data both within the United States and globally.</p>

Question 6:	How have you overcome barriers to implementing open standards?
	<p>The continued effort for consistent implementation of C-CDA documents has also been something ONC has been partnering with HL7 to address and has been a success (e.g. C-CDA Implementation-a-thons).</p> <p>Creating a suite of test tools to support the consistent implementation of the standards used in the US has helped drive towards our goal of interoperability. For example, FHIR testing suite can be accessed at Inferno and C-CDA validators can be accessed at SITE.</p>
Question 7:	What learning / advice would you like to share?
Canada	<p>Effective governance is needed: this should include not only clinical and technical but also legal, policy and sustainability aspects.</p> <p>All stakeholders must have some degree of skin in the game. Active engagement builds commitment.</p> <p>A strong communication strategy and engagement approach is key to continuously mobilising stakeholders through the life cycle of programmes.</p> <p>Building consensus on implementable, testable specifications not just base standards (HL7, LOINC, SNOMED CT, etc) is important. This includes learning by doing through collaborative real-life validation of the specifications from a technical and end user (clinical, patient) perspective.</p>
Germany	<p>Clear designation of responsible organisations and of standards can foster conversion of legacy implementations towards common standards but the process should allow for enough time and room for discussion of all engaged stakeholders.</p>
Italy	<p>It is very important to define national standards based on European standards to allow the exchange of documents and data not only among the Italian Regions but most importantly between the Italian Regions and EU countries.</p> <p>We should progressively avoid using / exchange pdf formats and start to use standard codes for clinical data, reducing the narrative parts of clinical documents.</p> <p>It is thus important to develop standards which are recognised internationally.</p>
Japan	<p>Japan is not yet in a position to provide advice.</p>
UK	<p>England and Wales: The standards used in any given system are a moving target. Strategies are required to meaningfully phase new standards in and out so that a national system isn't constantly in catch-up mode.</p>

Question 7:	What learning / advice would you like to share?
USA	Having a common set of data elements with expectations around terminology and structure has been instrumental in coalescing various industry activities toward meaningful health data exchange. The USCDI and the Standards Version Advancement Process have been developed to promote a common set of standards for information exchange and to update routinely as the industry progresses in standards adoption.

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