

Interoperability in Health

Digital technology, applications, data, and information systems, as part of the ongoing transformation of health and health care can help ensure universal and equitable access to affordable, people-centered, and integrated quality care, contributing to the goal of reaching Universal Health Coverage (UHC). Intelligent use of data and digital technologies can elevate patient experience, improve staff satisfaction, drive operational efficiency, improve patient outcomes, and create new business models, with benefits for both the public and private sectors.

This **Implementation Know-How Brief** provides World Bank Group **staff, country teams, and other organizations involved in the implementation of Digital-in-Health activities** with practical discussions, key terms and considerations, and broad guidance on how to engage with clients on the topic of **interoperability in health**.



This Brief Will Help Stakeholders to:

- Learn about **key terms and working definitions, different interoperability layers, and the importance of interoperability** in the health sector
- Learn how **different standards contribute to different interoperability layers** in health
- Understand how to **assess the current state of interoperability** in health in context
- Advise policy makers on how to **promote interoperability in specific projects** and in the health sector more broadly
- Understand what are some of the **challenges and pitfalls in achieving interoperability** in health

Why Is Interoperability in Health Important?

Imagine, for example, a hypothetical patient who has an insulin pump and a continuous blood glucose monitor, both with Bluetooth connections so that the patient's physician can remotely monitor their status. Imagine this patient visits their family who live in a remote location in a different jurisdiction. One day they become dizzy, fall, and hurt their wrist. They go to a local outpatient clinic, where the health care team determines that the patient needs a scan. The patient travels to the closest rural hospital for the scan. As there is no resident radiologist, the images are sent to a bigger hospital in a different jurisdiction. While waiting for the results, the patient also has blood tests done. Eager to speak with her usual primary care doctor, the patient has a teleconsultation and hears from her doctor that they should wait for the

radiologist's report. A few hours later, the radiology report comes back, and the patient is told that they will make a swift recovery and are prescribed a pain killer. The patient leaves the hospital and collects the medicine from a local pharmacy.

In this scenario, **different types of personal digital health data on this patient will have been created in several different locations** including blood glucose data from their monitor; fall detection data in their mobile phone; digital health record data in the outpatient clinic, the rural hospital, the bigger hospital, and their primary care physician; imaging data; laboratory data; pharmacy data; and insurance claims data from all providers that the patient consulted with. Furthermore, **medical services will have been provided across different jurisdictions and multiple organizations.**

Without interoperability (the ability of different organizational and digital systems to interact including through sharing of data), all these data would be confined to the systems and databases where they were collected, and services across jurisdictions might be limited. For the patient's endocrinologist (who manages their diabetes) to learn about the fall, they would have to rely on information given by the patient themselves. The patient may have printed versions of the scan and lab results, but without structure and proper coding of the medical information, the endocrinologist may not be able to interpret the results or may misinterpret them. Research studies using data on this patient may never know about the fall, nor have access to all the data in a standardized format. Economic studies may never be able to understand that all these visits to different providers were due to the same underlying cause. Without interoperability and standards, health data cannot be shared, and some services may not be provided, potentially leading to inefficiencies, slower progress in health research, ill-informed decision-making, inequities, incorrect understanding of diagnoses or medications, and potentially harm to patients (Lehne et al. 2019; Australian Digital Health Agency 2017).

With interoperability, services can be provided across jurisdictions, and health data can be shared and used to, for example, improve patient care and outcomes; to help empower patients to access and share their health information; to manage health system performance at various levels (national, organizational); to monitor public health; to open up new channels of communication with patients and communities; to enable new models of service delivery like electronic prescribing and telemedicine; to facilitate better targeting of reimbursement for services; to promote biomedical research and development; to stimulate innovations in data analysis (such as big data and machine learning) (OECD 2022). With interoperability, every data point collected for the hypothetical diabetic patient above could be used for multiple purposes, including for direct care, to assess health system performance, and many others. Examples of the many potential benefits of interoperability are shown in table 1.

Table 1 Examples of potential benefits of interoperability and standards in health**For patients and communities**

- More coordinated and integrated care
- Better quality of care and more personalized care
- Safer care, with less duplication of procedures, fewer adverse events, better monitoring of health status
- Patient privacy enabled by data protection standards
- Better patient experience and care transitions, patients are asked for their data only once
- Empowerment through access to patients' own digital health records

For health and care professionals

- Safer and more effective decisions based on comprehensive and up-to-date data on patients' health status
- Lower likelihood of wrong interpretation of data
- Greater efficiency of data collection and exchange
- Decision support tools that are built on evidence-based clinical guidelines
- Better coordination across different health care professionals and organizations

For health and care providers/organizations

- Increased efficiency, productivity, and quality of care
- Lower costs from avoiding duplicate tests and unnecessary consultations
- Systematic approaches to managing business risk
- Lower likelihood of technology and vendor lock-in

For researchers

- Access to big health data through linkage of health data sources, leading to more reliable analyses
- Faster and less costly research through reuse of existing real-world and clinical study data.
- Enhanced innovation and development of new treatments

For health authorities

- Easier implementation of public health surveillance and strategies, and pharmacovigilance
- Promoting optimal health services and resource planning
- Improved equity in access to quality care everywhere for everyone
- Easier to monitor health care provider performance, including safety and quality of care.
- Lower likelihood of fraud, unnecessary costs, and improved accuracy of data for funding and reimbursement
- Easier to share health data and information across borders
- More cost-effective to regulate and ensure compliance
- Increased adaptability and flexibility to changing circumstances

Table continued...

Table 1 Examples of potential benefits of interoperability and standards in health (continued)**For others (for example, industry)**

- Increased competition in the digital health care market, with a level-playing field.
- Lower implementation and integration costs.
- Less barriers to trade through harmonization of regulations across countries.
- Access to the knowledge and best practices of leading experts around the world

Source: Based on (World Bank 2019; Australian Digital Health Agency 2017) as well as multiple online sources¹.

What is Interoperability?

Task Teams should be aware that different organizations and countries have different definitions for interoperability. The World Health Organization (WHO) defines interoperability as “the ability of different applications to access, exchange, integrate and cooperatively use data in a coordinated manner through the use of shared application interfaces and standards, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize health outcomes” (World Health Organization 2021). The European Union (EU) takes a broader view of interoperability defining it as the “the ability of organizations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organizations, through the business processes they support, by means of the exchange of data between their information and communication technology systems” (European Commission Directorate General for Informatics 2017). The European Interoperability Framework (EIF) thus contains four interoperability layers: legal, organizational, semantic, and technical. The World Bank’s GovTech project—which focuses on interoperability in the public sector—also considers interoperability a **layered concept, consisting of elements with a digital and nondigital focus** (as shown in table 2) (World Bank 2022).

Table 2 Interoperability layers**Cross-cutting governance layers**

Interoperability governance	Concerns decisions on interoperability frameworks, institutional arrangements, organizational structures, roles and responsibilities, policies, agreements, and other aspects of ensuring and monitoring interoperability
Integrated service governance	Focuses on the planning, implementation, and operation of the public services that build on integration, seamless execution, and the reuse of services and data

Table continued...

Table 2 Interoperability layers (continued)**Non-digital interoperability layers**

Legal interoperability	Is about ensuring that organizations operating under different legal frameworks, policies, and strategies can work together, for example, by establishing specific agreements or putting in place new legislation
Organizational interoperability	Refers to the way in which public administrations align their business processes, responsibilities, and expectations to achieve commonly agreed and mutually beneficial goals
Cultural interoperability	Refers to the approach taken by individuals and organizations to align their social and cultural differences and, if applicable, organizational cultural differences, all of which can be at the root of different responses to the same interoperability challenge

Digital interoperability layers

Semantic interoperability	Refers to the ability of different information technology systems and software applications to automatically interpret the information exchanged meaningfully and accurately to produce useful results
Syntactic interoperability	Describes the exact format of the information to be exchanged in terms of grammar, format, and schemas.
Technical interoperability	Covers the applications and infrastructures linking systems and services, such as interface specifications, interconnection services, data integration services, data presentation and exchange, and secure communication protocols.

Source: Based on (World Bank 2022) and HIMSS webpage on interoperability in health (available from <https://www.himss.org/resources/interoperability-healthcare>).

Under the EU and World Bank's definitions of interoperability, **exchange of information and data between information and communication technology systems is not sufficient to advance interoperability**. It is also necessary to address legal, organizational, and cultural interoperability, all under cross-cutting governance layers. This brief adopts this broader and layered notion of interoperability².

What are Standards?

Standards are a key element of interoperability, in all its layers. Put simply, "standards are agreed-upon conventions for doing something" (Sansone and Rocca-Serra 2016). By providing a common language and a common set of expectations, standards enable different systems and devices to work together; they enable interoperability.

Standards are very heterogeneous, including testing methods; performance standards; codes of practice; management system standards; service standards; recommendations and guidelines on best practices; conformity assessment practices; certification of persons; graphical symbols; etc. (see annex for more details)³. There are many stakeholders that are involved in the development of standards, that use standards, and that are affected by standards, including, for example, physicians and nurses; patients; hospitals, pharmacies and

laboratories; medical device manufacturers; governmental agencies; and insurance companies (ENISA 2019).

Generally, **standards can be developed, adapted, or simply adopted:**

- **Standards are developed when no standard exists that can be simply adopted,** and it would be infeasible to adapt an existing standard. While it is unlikely that an existing standard cannot be adopted or adapted, in practice many standards are custom-built for specific deployments, even sometimes mimicking existing commonly accepted standards
- **Standards can be adapted when an existing standard cannot be adopted** outright but can be modified as it covers a subset or a superset of health system needs or workflow goals. This requires fewer resources (time and money) than developing a standard and ensures that well-designed and thoroughly tested and maintained standards are used
- **Standards can be simply adopted when an existing standard covers the health system needs or workflow goals.** This requires even fewer resources than adapting a standard and has the same benefits related to the use of high-quality well-designed standards

Standards are typically adopted, adapted, or developed by consensus among interested parties and approved by a recognized body; they can be voluntary or mandatory, depending on whether there are laws or regulations to enforce their adoption and use (for example, for health and safety)⁴. A brief description of how standards are developed is provided in annex

Advancing Interoperability in Health

With the health sector increasingly reliant on digital technologies and assets, **it is incumbent on governments to advance interoperability in their national digital health information systems.** The WHO Global Strategy on Digital Health 2020-2025 includes in its objectives for the medium-term (2 to 4 years) Member States' approval of a WHO guideline on global interoperability standards for digital health to serve as the basis for orientation for national legal and regulatory frameworks (World Health Organization 2021). Task Teams should note the following basic assumptions when advising clients on how to promote interoperability in health:

- **Government should play a leading role but interoperability in health hinges on partnerships.** Sources of health data are increasingly distributed, including the Internet of Medical Things, remote patient monitoring, hospital at home, and even mobile phones. Private health care providers, laboratories, pharmaceutical companies, medical device manufacturers, and others, all collect and use health data. Even in countries with a public single payer and majority public care provision, the government and the public sector must partner with patients and the private sector
- **Every country is starting from a different baseline interoperability maturity, context, and capacity.** There are many ways to promote interoperability within a

given context, based on the existing institutions and information and communication technologies in place. While mechanisms (for example, the use of standards) to promote interoperability may be general across countries and contexts, the exact instruments (for example, enforcement of standards) used in practice will differ from country to country and context to context. There is no one-size-fits-all path to interoperability, and different approaches will work better in different contexts

- **Interoperability does not stop at the national border.** Cross-border exchange of health data and information not only allows patients to receive health care when abroad but can also promote research and development by increasing the amount of data available (this is especially helpful for research on rare diseases). Some standards are already trans-national (for example, HL7) and initiatives like IHE International, the Global Digital Health Partnership, and the European Health Data Space, are trying to establish international agreements on digital interoperability (semantic, syntactic, and technical)

As with all interventions in the digital health space, the development, adoption, adaptation, implementation, and monitoring of standards and interoperability in health should be well-aligned with the Principles for Digital Development⁵, specifically: designing with the user; designing for scale; using open standards, open data, open source, and open innovation; addressing privacy and security; and being collaborative.

Key Considerations for Policy Makers in Health

To help make the considerations below more practical, imagine that a country is seeking to implement electronic prescribing or ePrescribing (the use of information and communication technology to generate, transmit, and fill medical prescriptions without the need for paper). This example will be used throughout the sections below to illustrate how policy makers can promote interoperability in health. As a starting point, the World Bank has identified the following **four key questions for any project seeking to advance interoperability** (World Bank 2022):

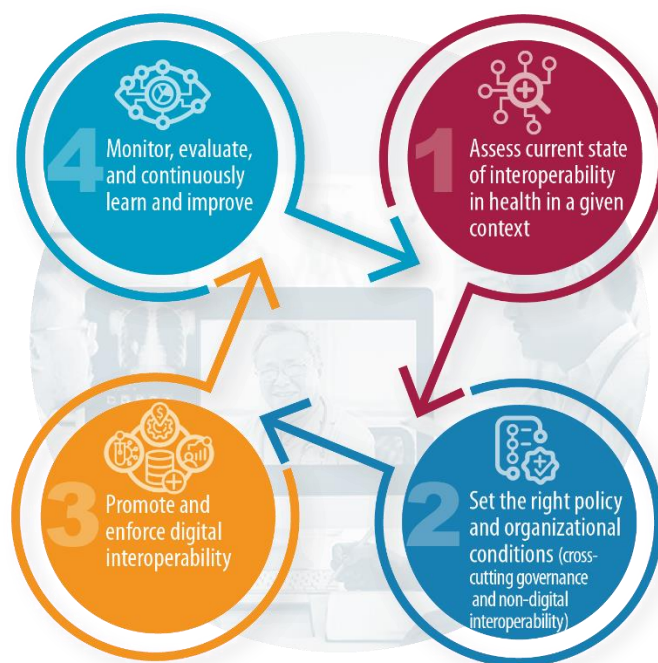
- **Goal-orientation:** What is the overall goal and scale of the interoperability project, in terms of both user needs and strategic objectives? For example: ePrescribing requires different layers of interoperability, from legal interoperability (for example, controlled substances may only be prescribed under certain conditions) to technical interoperability (for example, prescribing and dispensing are linked using GS1 barcodes)
- **Co-creation:** Which actors should be involved to make the project a success, in terms of both expertise and support, and what are their needs? For example: citizens, frontline health care workers, health care organizations, pharmaceutical companies, pharmaceutical regulator, etc.
- **Context sensitivity:** What is the most viable course of action considering the country context, a specific organization's accomplishments, and available resources? For example: what are the most appropriate ways to promote ePrescribing interoperability

in all its layers given the context (for example, making standards mandatory, having a software certification process, auditing health care providers, introducing financial incentives, all of the above)

- **Iteration:** How are different digital interoperability layers related, and what does this mean for the specific project? For example: will the adoption of semantic interoperability standards require actions to address cultural interoperability to ensure that health care workers are on board with plans

Figure 1 illustrates **the broad process for advancing interoperability in health**, in all its layers, in context. Starting with a broad assessment of the current state of interoperability in a specific context is key to developing a strategy that allows decision makers to set the right policy and organizational conditions in place (non-digital interoperability) and to promote and implement digital interoperability (semantic, syntactic, and technical). Advancing interoperability in health is not a destination, but rather a journey of continuous learning and improvement. Like chronic disease management, it also requires strong preventative practices and regular foci such as compliance-testing. Concrete solutions for advancing interoperability—including the adoption and use standards—should be reviewed regularly to ensure that they remain useful.

Figure 1 Key steps for policy makers seeking to advance interoperability in health



Given the basic assumptions highlighted above, specifically that interoperability in health requires partnerships and does not stop at national borders, having a **national organization, governed by a multidisciplinary body with wide stakeholder representation, with primary responsibility for interoperability in health** could be productive⁶. Such an

organization could be newly created, or its functions could be performed by an existing organization (for example, a digital health agency, a health data authority, a ministerial department). In countries with devolved responsibilities in health, subnational agencies could be responsible for interoperability in health, although it is always advisable that subnational agencies coordinate at national level. Such a national organization would be responsible for implementing in practice the steps and considerations provided below. As such, the text below will reference such a national organization whenever appropriate.

1 Assessing the Current Situation and Baseline Maturity



Recalling that interoperability projects must have clear goals and be context-specific, the first step is to conduct a **situational assessment of the current level of interoperability maturity in context**. In this first step, the World Bank Task Teams and the client(s) would work together to determine what the assessment will accomplish and how its results will be used to inform decisions to advance interoperability in health. **Creating a committee to conduct the initial investigations** is advisable. The assessments should help characterize the level of interoperability maturity in context, including how standards are currently developed, adapted, or adopted, as well as implemented, and monitored. For assessments of baseline digital interoperability (semantic, syntactic, and technical) in low-resource settings specifically, MEASURE Evaluation and the Digital Health and Interoperability Technical Working Group of the Health Data Collaborative have developed a Health Information Systems Interoperability Maturity Toolkit (see annex)⁷.



Task teams and clients should seek and review previous assessments (including broad digital health maturity assessments) to fill in gaps and achieve efficiencies (to avoid conducting unnecessary duplicative assessments)

To understand how standards related to interoperability in health are being developed, adapted, or adopted, as well as implemented, and monitored, it **is important to engage with the country's National Standards Body (NSB)**. As the leading national SDO, the NSB should be actively engaged in any situational assessment of standards for interoperability in health. Working with the NSB, it should be possible to identify existing national standards that relate to interoperability in health, stakeholders involved in the development, adaptation, or adoption of these standards, and effective implementation and use (voluntary or mandatory) of these standards in the health care sector (including both public and private organizations).

Regardless of what toolkits or frameworks are chosen to conduct the situational assessment of interoperability in health, **the WHO/ITU building blocks for electronic/digital health** are useful and can complement existing frameworks (see the table in annex). To help make these initial considerations more practical, recall the example of a country that is seeking to implement ePrescribing. Table 3 suggests some of the questions that Task Teams and client(s)

should consider, for each of WHO/ITU's building blocks, in such a project, to illustrate in practice why a baseline assessment is important.

Table 3 Example of WHO/ITU's building blocks and interoperability in electronic prescribing

Building block: Legislation, policy, and compliance

- Can ePrescribing data be used for public health surveillance and academic research studies?
- Can ePrescriptions be legally transmitted from prescribing health workers to dispensing pharmacists?
- Is there accreditation and certification of vendors of ePrescribing software?

Building block: Leadership and governance

- Is there a national interoperability framework that can be applied to ePrescribing?
- Are there plans to engage key stakeholders (for example, clinicians, patients, pharmacists, regulators) and keep them engaged throughout the process?

Building block: Interoperability and standards

- Are there voluntary or mandatory digital standards to generate and transmit ePrescriptions?
- Are there voluntary or mandatory guideline-adherent care standards related to ePrescribing?
- Is there a plan to migrate or sunset existing ePrescribing systems that do not meet digital interoperability standards?

Building block: Workforce

- Are there staff with the necessary skills, experience and knowledge required to design, build, operate, support, manage, and maintain interoperable ePrescribing systems, services, and applications?

Building block: Strategy and investment

- Is there an overarching digital strategy to tie interoperability standards for ePrescribing with health systems goals and challenges (for example, using ePrescribing to promote generics to in turn promote value for money)?
- Is there a funding mechanism for the implementation of interoperability in ePrescribing, including standards?

Building block: Infrastructure

- Is there physical computing infrastructure (for example, servers or cloud services) to support exchange of ePrescriptions and other ePrescribing data?
- Is current access to electricity and Internet connectivity appropriate for data exchange across systems?

Building block: Services and applications

- Are there registry services used to provide mutually exclusive and collectively exhaustive terminologies that are used in ePrescribing (for example, lists of medicines, master patient index, health care worker registry)?
- Are there authentication services for secure transmission and delivery of ePrescriptions and ePrescribing data?

Source: World Health Organization and Union 2012; DICE 2022.

Note: See annex for questions unrelated to ePrescribing.

2 Setting the Policy and Organizational Conditions: Cross-Cutting and Non-digital Interoperability Layers



Following an initial situational assessment, the next step is to set the policy and organizational conditions for advancing interoperability in health. Recall that exchange of information and data between information and communication technology systems is not sufficient to advance interoperability. It is also necessary to address legal, organizational, and cultural interoperability, all under cross-cutting governance layers. **This section focuses on cross-cutting governance layers and layers of non-digital interoperability (legal, organizational, and cultural).** Table 4 highlights some of the ways in which policy makers in health can set the right policy and organizational conditions to advance interoperability in specific projects and in the health system more broadly.

Table 4 Setting the policy and organizational conditions to advance interoperability

Creating the Basis for Operations: Policy and Institutional Setting

- Embed interoperability in the overall digital health strategy
- Establish the institutional structure with leadership to support interoperability (for example, a national organization, governed by a multidisciplinary body with wide stakeholder representation, with primary responsibility for interoperability in health)
- Ensure solid coordination mechanisms to prioritize interoperability

Ensuring Proper Legal and Regulatory Frameworks

- Include diverse domains such as privacy and data protection, data standards, right to information, the application of the once-only principle, and data ownership and consent
- Secure proper regulation of digital health and ensure that citizens' interests and rights are legally covered
- Develop a proper assessment of the existing situation of the legal and regulatory framework*

Setting up Trustworthy Health Data Governance

- Focus on guiding data-driven value creation
- Enhance trust, ethics, and data rights in digital health

Promoting a Health Data Culture and Cultural Interoperability

- Ensure clear leadership and institutional coordination to promote the required systems thinking approaches for a data-driven health sector
- Recognize the role of organizational and individual incentives

Table continued...

Table 4 Setting the policy and organizational conditions to advance interoperability (continued)**Using Policy Levers for Coherent Implementation**

- Adopt pre-evaluation of information and communications technology investments and public procurement to make sure that specific requisites such as interoperability standards are properly addressed
- Implement Standard Business and Use Cases and possibly Standardized Project Management practices
- Improve capacity for monitoring and evaluation

Fostering Digital Skills and Talent

- Define the right option to foster digital skills from building (upskilling a reskilling), buying (recruiting), or borrowing (temporary staff, redeployment, secondment)
- Modernize human resources management policies and practices to assure the necessary interoperability and skills are available

Source: Based on World Bank 2022)

Note: * This step can be conducted in the initial situational assessment; Under the once-only principle, citizens and businesses are asked to provide their data only once.

As mentioned, having a national organization, governed by a multidisciplinary body with wide stakeholder representation, with primary responsibility for interoperability in health could be productive. Such an organization could serve several important functions. It could **develop a framework for interoperability in health** with guidance on how to set up interoperable health information and communication systems, or it could contribute to a national interoperability framework developed by central government. The World Bank ID4D project's requirements for building interoperability frameworks in Table 5 may be helpful.

Table 5 Requirements for building interoperability frameworks

Layer	Requirements
Legal interoperability	<p>Perform "interoperability checks" by screening existing legislation to identify:</p> <ul style="list-style-type: none"> ▪ Interoperability barriers: Such as sectoral or geographical restrictions in the use and storage of data, different and vague data license models, over-restrictive obligations to use specific digital technologies or delivery modes to provide services, contradictory requirements for the same or similar business processes, outdated security and data protection needs ▪ Coherence: Evaluate compatibility between the enabling legislation of different organizations to ensure interoperability ▪ Digital applicability: Ensure that legislation suits digital (as well as physical) health data processing

Table continued...

Table 5 Requirements for building interoperability frameworks (continued)

Layer	Requirements
Organizational interoperability	<p>Define inter-organizational relationships and processes:</p> <ul style="list-style-type: none"> Organizations must align their business processes, responsibilities, and expectations to achieve commonly agreed and mutually beneficial goals and document them Clearly define relationship between product and service providers and consumers for example, memorandums of understanding (MoU's), Service Level Agreements (SLAs), API specifications, etc.
Semantic interoperability	<p>Adopt data standards to be used by organizations in the interoperability framework:</p> <ul style="list-style-type: none"> Develop semantic vocabularies and schemata to describe data exchanges and ensure that data elements are understood in the same way by all communicating parties Define syntactic format of the information to be exchanged in terms of grammar and format
Syntactic interoperability	<p>Adopt data standards to be used by organizations in the interoperability framework:</p> <ul style="list-style-type: none"> Define syntactic format of the information to be exchanged in terms of grammar and format
Technical interoperability	<p>Adopt technical standards to be used for system components and devices:</p> <ul style="list-style-type: none"> Use open specifications, where available, to ensure technical interoperability Put in place processes to select relevant standards and specifications, evaluate them, monitor their implementation, check compliance, and test their interoperability Use a structured, transparent, objective, and common approach to assessing and selecting standards and specifications, considering the requirement to make them consistent across borders Consult relevant catalogues of standards, specifications, and guidelines at national and regional level, when procuring and developing information and communication technology solutions
Integrated public service governance	<p>Throughout the above layers, ensure coordination and documentation of:</p> <ul style="list-style-type: none"> The definition of organizational structures, roles and responsibilities and the decision-making process for the stakeholders involved The imposition of requirements for aspects of interoperability including quality, scalability, availability, service level agreements, security, and privacy controls Change management plans that define the procedures and processes needed to deal with and control changes Business continuity/disaster recovery plans to ensure that digital public services and their building blocks continue to work in a range of situations (for example, cyberattacks or systems failures)

Source: Based on World Bank 2019.

An organization with oversight of interoperability in health could also **advise policy makers**, including, for example, on whether to make certain interoperability standards mandatory through regulation or legislation, and how to adopt interoperability-by-design (have interoperability and reusability requirements in the design stage). It could also **provide training courses** for all stakeholders (for example, policy makers, health care providers, industry, the public) on standardization and interoperability in digital health. Setting up an interoperability portal could also be a way to increase the reach and impact of an interoperability framework for health (European Commission Directorate-General for Informatics 2022).

An organization with oversight of interoperability in health could also be responsible for setting, incentivizing, and enforcing the use of national/subnational standards for interoperability in health, including digital interoperability standards (for example, content, terminology, messaging, etc.) but also non-digital standards (for example, standards of care, standard operating procedures, etc.), and support the NSB at national and international level in matters related to digital health. Crucially, it could establish **a clear process for developing, implementing, and monitoring national standards for interoperability in health**, with broad engagement of key stakeholders (sometimes called the Interoperability Standards Advisory or ISA process). For example, in Canada, *eHealth Ontario* standards development process may provide some ideas⁸:

- 1 **Need identification and business definition:** a standard is requested
- 2 **Options research and analysis:** can an existing standard be re-used or a new one is needed?
- 3 **Solutions development:** consultation, research, and development with broad engagement
- 4 **Testing and pilot:** pre-production models/versions are tested
- 5 **Training and education:** materials are developed and distributed to all interested parties
- 6 **Implementation:** supported by tools, guidelines and advice are provided to support
- 7 **Conformance:** checking for proper implementation and lessons learned to inform revisions
- 8 **Maintenance and support:** regular reviews and updates to ensure standards remain useful

As mentioned, it is important to **frame interoperability in health as part of a broader national health data governance framework**. Data are a double-edged sword (World Bank 2021): they have massive potential for both creating social and economic value as well as for concentrating economic and political power to the detriment of citizens. Interoperability and the use of standards promote the use and reuse of data as crucial to achieving benefits, but the more data are used and reused, the greater the potential for abuse. This is why data governance frameworks are important, especially in the context of sensitive data concerning health. Data governance frameworks foster trust, create robust processes to enable data sharing while protecting individual privacy, and can promote ethical, responsible, quality

management of data across the data journey⁹. Particularly relevant for interoperability, a health data governance framework would clarify a patient consent model for health information, which is crucial for trustworthy sharing and use of health data.

Finally, efforts to set the policy and organizational conditions to advance interoperability in health should be coordinated and aligned at national level, and across sectors, with other initiatives to advance interoperability (for example, frameworks for interoperability in the public sector).

EXAMPLE: Setting policy and organizational conditions for electronic prescribing

- Establish the institutional structure with leadership to support interoperability, and involve all relevant stakeholders (including patients, health care providers, pharmacists, pharmaceutical regulators, Ministry of Health, and others)
- Ensure proper legal and regulatory framework to allow prescriptions to be generated and transmitted electronically
- Consider organizational and individual incentives to, for example, bring providers and pharmacists along
- Define the right option to foster digital skills among users (for example, prescribers)
- Align interoperability requirements for ePrescribing with (existing) national data governance framework(s)

3 Promoting and Enforcing Digital Interoperability

With the right policy and organizational conditions in development or in place, policy makers can **focus on advancing digital interoperability in health (semantic, syntactic, and technical)**. Table 6 highlights some of the ways in which policy makers in health can promote and enforce digital interoperability in specific projects and in the health system more broadly.

Table 6 Advancing digital interoperability in health

Ensuring data readiness

- Understand what data are needed and available, what is trying to accomplished by using the data, and why and who can and needs to access the data
- Develop a data strategy that may require a current state baseline assessment*
- Establish data governance to ensuring data quality, integrity, availability, harmonization, legal and regulatory frameworks, and overall management of data

Anticipating key technology trends

- Understand new technology trends and how they might create a need to rethink interoperability
- Identify new challenges through the lenses of technology, people, process, and ecosystem

Table continued...

Table 6 Advancing digital interoperability in health (continued)**Adopt an enterprise architecture approach and harness interoperability technologies**

- Incorporate interoperability considerations in all elements of the Enterprise Architecture: the business architecture, the data architecture, the application architecture, and the technology architecture
- Consider implementing a Digital Health Platform (DHP)
- Consider adopting Application Programming Interfaces (APIs) and Enterprise Service Buses (ESB)
- Understand cybersecurity considerations for harnessing APIs

Working with open standards and open source

- Ensure that interoperability is open to new software modules and new providers, and avoid lock-in
- Encourage sharing of code as open source and publishing of standards as open standards
- Benefit from already published open-source material and open standards to develop interoperability initiatives

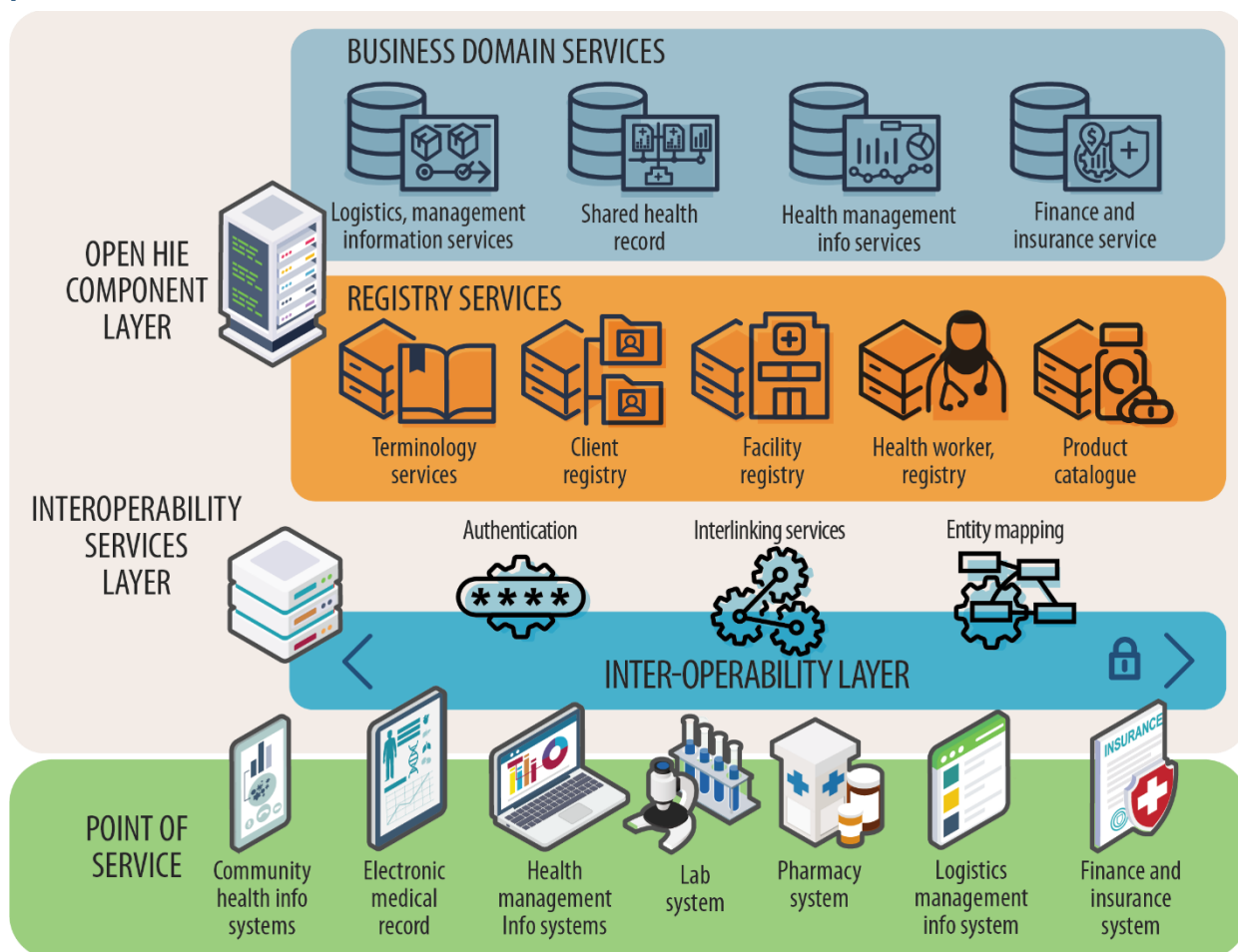
Source: Based on World Bank 2022; World Health Organization; International Telecommunication Union 2020; TOGAF Standard interoperability requirements available from <https://pubs.opengroup.org/architecture/togaf9-doc/arch/chap25.html>.

Note: * = This step can be conducted in the initial situational assessment.

Policy makers in health—perhaps through an organization with oversight of interoperability in health—could **support organizations in the sector to conduct assessments of their data and systems readiness and to adopt an enterprise architecture approach** (assessments at this stage are organizational and thus separate and distinct from assessments at policy level discussed above). An enterprise architecture approach steers interoperability that serves users and their respective workflows in the health care system such as patients, providers, health system managers. It enables the workflows (including data) that various stakeholders need to ensure accountable, high-quality, guideline-adherent care. Approaches and technologies that allow interoperability across existing individual systems as well as new applications and services that may be in the process of being implemented today or in the future are important. One such approach is the Digital Health Platform (DHP) (World Health Organization and International Telecommunication Union 2020). A DHP approach (as illustrated in figure 2 by OpenHIE architecture) can:

- Enable interoperability of digital health applications through information flow and reduces fragmentation of applications in the health sector
- Consolidate information from appropriate business domain or registry services
- Accelerate innovation in digital health applications through use of common shared functions
- Accelerate the design and implementation of digital health interventions, which enable the health sector to achieve its goals in a more predictable, efficient, and cost-effective manner and with reduced risk

Figure 2 The OpenHIE architecture: a type of deployment approach for a digital health platform



Source: OpenHIE's architecture diagram available from <https://guides.ohie.org/arch-spec/architecture-specification/overview-of-the-architecture>.

WHO highlights three types of deployment approaches: single system (centralized), two-way integration, and interoperable (as shown in annex).

An organization with oversight of interoperability in health could take a **leading role in assessing and selecting standards, promoting the use of open standards, providing roadmaps for implementation of standards, and enforcing effective use**. The EU's Common Assessment Method for Standards and Specifications (CAMSS) may be helpful. CAMSS is a "guide for assessing and selecting standards and specifications for an eGovernment project, a reference when building an architecture and an enabler for justifying the choice of standards and specifications in terms of interoperability needs and requirements"¹⁰. CAMSS seeks to avoid "vendor lock-in by establishing a neutral and unbiased method for the assessment of technical specifications and standards in the field of information and communication technologies". Promoting the use of open standards could result in lower long-term costs and greater flexibility, control, and ownership for all stakeholders (World Bank 2019). It would be helpful to organizations involved in health to maintain and publish a list of all standards for interoperability in health, and implementation specifications, with useful

information for interested parties. For example, the United States ISA includes the following information in its list¹¹:

- **Adoption Level:** Approximate, average adoption level for a specific use case in health care
- **Cost:** Is a fee necessary to purchase, license, or obtain membership for access or use of the recommended standard or implementation specification?
- **Federally Required Status:** Has a standard or implementation specification been adopted in regulation, referenced as a federal program requirement, or referenced in a federal procurement (contract or grant)?
- **Implementation Maturity:** Level of maturity based on implementation state.
- **Standards Process Maturity:** Level of maturity in terms of stage within a particular organization's approval/voting process
- **Test Tool Availability:** Is a test tool available to evaluate health information technology's conformance to the standard or implementation specification?

Standards for interoperability in health on their own are helpful, but to be truly beneficial at scale, interoperability standards need to be implemented and used widely, by both the public and private sectors. This is why it is vital to **develop, publish and disseminate implementation roadmaps, guides, or profiles**. These roadmaps or guides describe how to use a standard to satisfy a specific health care use case (for example, filling an electronic prescription, reporting an infection with a drug-resistant bacterium, etc.). The value of implementation roadmaps and guides that focus on a specific use case is that they reduce ambiguity and promote consistency in implementation. For example, New Zealand's Health Information Standards Organisation develops adoption roadmaps for all new standards¹². The previously mentioned IHE Profiles, for example, provide precise definitions of how to implement standards to meet specific clinical needs; offer developers a clear implementation path that has been carefully documented, reviewed, and tested as well as supported by industry partners; and give purchasers a tool that reduces the complexity, cost, and anxiety of implementing interoperable systems¹³.

Finally, there are several mechanisms for government to **promote compliance and enforce the use of digital interoperability standards** by both the public and private sectors, including (OECD 2022):

- **Legislation and regulation** requiring that certain digital interoperability standards (semantic, syntactic, technical) be used by, for example, all health care providers. Through legislation and regulations, governments can make the use of interoperability standards mandatory. Laws can also be used to control access to national health information and communication systems, services, and applications
- **Certification processes** to establish that vendors of health information systems (such as electronic health record systems) conform with digital interoperability standards. Certification can be used to signal to stakeholders that vendors meet interoperability requirements (even when these are not mandated) or to ensure that only vendors that

meet mandated requirements (in legislation or regulations) are allowed to operate (are licensed)

- **Audits** to determine whether stakeholders are adhering to mandated interoperability requirements. Non-compliant stakeholders may be given a warning, a penalty or even lose their license to operate
- **Financial incentives and penalties** for stakeholders to adopt digital interoperability standards or to purchase software from vendors certified to conform to interoperability requirements. An example of a financial incentive is to give health care providers financial payments in exchange for use of certified software or proof of conformity with interoperability requirements. An example of financial penalties in countries with national health insurance schemes is denial of reimbursement if a health care provider does not meet interoperability requirements

Multiple mechanisms can be combined (for example, legislation can be combined with certification). The exact instruments used to operationalize these mechanisms are many, and there is limited evidence of which instruments work best in what contexts. It is important to **keep in mind cross-cutting and non-digital interoperability layers such as governance, legal and cultural interoperability** when determining how to enforce compliance with digital interoperability standards. For example, enforcement requires investment, or it can become an unfunded mandate. Compliance with non-digital interoperability standards (such as guideline-adherent care) is also vital but tends to be the responsibility of existing institutions tasked with regulating and overseeing care quality and safety.

EXAMPLE: Advancing digital interoperability for electronic prescribing

- Establish how ePrescribing fits within the Enterprise Architecture (the business architecture, the data architecture, the application architecture, and the technology architecture) and implications for digital interoperability
- Adopt, adapt, or develop semantic, syntactic, and technical interoperability standards
- Develop, publish, and disseminate implementation roadmaps, guides, or profiles for ePrescribing standards
- Adopt mechanisms to promote compliance and enforce the use of digital interoperability standards (for example, legislation and regulations, certification, auditing, and financial incentives)

4 Continual Monitoring, Evaluating, Learning, and Improving



As mentioned, advancing interoperability in health is not a destination, but rather a journey of continual monitoring, evaluation, learning and improvement. At the level of the cross-cutting layers of interoperability governance and integrated service governance, concrete solutions for non-digital and digital interoperability – including standards – should be reviewed frequently to ensure that they remain useful. New technologies and other developments (for example, new legislation or regulation on cybersecurity or data governance) should prompt reviews of current arrangements, looping back to the assessment stage (and potentially also to assessments at organizational level).

Implementation of standards for interoperability in health is not a linear process. Before widespread implementation at scale, and certainly before adoption of standards in regulations/legislation, **standards are tested and piloted in the real world, and the lessons learned from this process are fed back into the process of developing, adapting, and adopting standards.** Different testing and compliance efforts include¹⁴: *conformity assessments* (which can be used to certify products and services as meeting the requirements of standards), *connectathons* (for example, such as HL7 FHIR or IHE connectathons where many stakeholders meet to engage in developing and testing of standards and profiles), and *national certification programs* (for example, the United States Office of the National Coordinator for Health Information Technology voluntary certification program). The timings of different review processes should be decided in context but, as an example, connectathons could run semi-annually while certification processes could have a quarterly window to support the private sector. New developments that require a rethink of interoperability (for example, new cybersecurity threats, new legal requirements, new standards) should trigger an out-of-cycle reaction.

As stated in the previous section, there are many mechanisms to promote compliance and enforcement of the use of interoperability standards. These should be well-funded and applied systematically. **Cross-cutting governance of interoperability is crucial** here to ensure that institutional mandates and arrangements are in place to effectively promote compliance and enforcement of the use of interoperability standards. Again, having an organization with oversight of interoperability in health would be beneficial and contribute to clarity of roles and responsibilities.

Monitoring, evaluation, and learning are crucial to ensuring that strategies to advance interoperability in health are achieving their intended goals, are comprehensive, and are not leading to unintended consequences. A step in this process is determining what success looks like, how it will be measured, and what are the key indicators that need to be collected, potentially for the first time ever. Monitoring and evaluation should then lead to continuous learning and improvement. The Pan-American Health Organization (PAHO) suggests **several indicators to monitor interoperability in health** (see table 7).

Table 7 Indicators for monitoring interoperability of digital health systems**Cross-cutting governance layers**

National plans and public policies	<ul style="list-style-type: none"> Existence of a national strategic plan, harmonized and integrated among multisectoral stakeholders
Investment or action	<ul style="list-style-type: none"> Existence of a budget for a digital agenda accompanied by the human resources, processes, legal-ethical framework, knowledge, and technology necessary for its effective operation Proportion of the digital health budget allocated to the areas of primary health care

Non-digital interoperability layers

Training	<ul style="list-style-type: none"> Existence of an interdisciplinary team of people who are trained and updated on good practices and standards Existence/implementation of maturity assessment guides that make it possible to evaluate, measure and accredit Number of learning spaces and exchange in interoperability standards Number of learning spaces agile methodologies and change management Number of publicity campaigns on the importance of health literacy
Data Governance	<ul style="list-style-type: none"> Existence and regular operation of a community of practice led by the ministries of health where knowledge is shared, increasing awareness, and understanding of information and communication technologies in the health area, and promoting synergies and disseminating best practices, including free developments to make services available to actors without acquisition or development capacity Existence of a certifying body that validates the norms, standards, safety, and quality of the systems to be implemented in the health area

Digital interoperability layers

Networks and sustainable development	<ul style="list-style-type: none"> Jurisdictions with regulations on the right of individuals to security, privacy, and confidentiality of their health data Providers of systems or services in the field of health that guarantee compliance with regulations
Infrastructure	<ul style="list-style-type: none"> Existence of interoperability practices between health platforms Existence of integrated national repositories of data from different sources
Standards	<ul style="list-style-type: none"> Existence of regulations and legal agreements that specify the scope of information that must be shared within secure environments with different levels of access to health data Existence of tools and regulatory frameworks in pursuit of promoting the autonomy of patients in the use of their own health information Number of data exchange agreements based on a legal framework and according to a plan, considering ethical and regulatory aspects, incentives, and obligations of each sector

Table continued...

Table 7 Indicators for monitoring interoperability of digital health systems (continued)**Digital interoperability layers**

Standards	<ul style="list-style-type: none"> Data policies and databases identified for decision-making at the managerial and public health level, which allows their secondary use for the generation of scientific knowledge or for the evaluation of services Existence and implementation of a procedural manual for continuous improvement and monitoring of data quality
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Source: Based on PAHO 2023; World Bank 2022.

Final Considerations

While not specific to the health sector, and while only focused on the public sector, the World Bank's GovTech Interoperability Know-How Note provides a Checklist for a Sound Interoperability Approach, with priorities across all modules of non-digital and digital interoperability set according to GovTech maturity levels (World Bank 2022).

Key Challenges and Pitfalls

The following interoperability challenges have been identified (World Bank 2022):

- **Trust and security:** Ensuring that data security and privacy are maintained when datasets and APIs are opened up and maintaining the integrity of underlying systems and data.
- **Financial resources:** Limited institutional financial capacity and a potential decline in revenues due to new approaches that do not involve charging other entities for access to data or systems.
- **Legacy technology:** Managing interoperability with legacy systems that may support only certain methods of integration or architectural approaches.
- **Human resources:** Need to upskill staff to adapt to new architectures.
- **Data quality:** Messy or incomplete datasets that require careful review and assessment before they can be made accessible to other systems and entities.
- **Data discoverability:** Difficulty knowing what relevant data are already available through APIs.
- **Process agreements and global coordination:** Inability to implement interoperability due to lack of systemic governance, shared processes, and common standards.
- **Inability to scale:** Challenges moving from small, one-off interoperability efforts to a broader and more systematic approach.
- **Varying levels of digital maturity across the sector:** Dealing with a heterogeneous health sector environment in terms of digital adoption and organizational readiness.

- **Political leadership and institutional engagement:** Ensuring all related agencies' participation and budget investment.

Other examples of challenges in advancing interoperability in health are shown below. Barriers to interoperability collected by the Global Digital Health Partnership are shown in the annex.



ISSUES AND CHALLENGES IN ADVANCING INTEROPERABILITY IN HEALTH

There is no central authority for interoperability and standards in health

There are too many interoperability standards in use, and some of them are in conflict

There is no national health data governance framework

There is limited, or unequally distributed, interoperability infrastructure and services/applications in use

Limited training, education, and instructional materials

Limited technical support provided to health care providers seeking to implement interoperability standards. There are no implementation roadmaps, guides, or profiles

Lack of funding mechanisms to ensure sustainability of authorities governing interoperability and standards

No unique patient identifier at national level

Prevalence of proprietary interoperability standards

Questions concerning legacy systems and systems in development that do not meet interoperability standards

Limited participation from private sector health stakeholders in interoperability efforts and standards setting

Poor usability of software products and impact on health care workers' workflows

Challenges in managing and coordinating actions across multiple stakeholders

Health care provider costs associated with software licenses and upgrades, retraining, and productivity losses

Lack of economic incentives to exchange health data

Lack of capacity and capabilities to act based on exchanged data

Interoperability standards development process is not clear nor is the role of government well understood

Certain interoperability standards (for example, clinical document architecture) are difficult to implement

Lack of guidance on what are the key interoperability standards that should be implemented

Low- and middle-income countries do not have contextualized digital health terminology standards

Source: Sansone and Rocca-Serra 2016; Ndlovu, Scott, and Mars 2021; Wilson 2019; Global Digital Health Partnership 2020; Australian Digital Health Agency 2017; Kiwanuka, Amiyo, and Nabukenya 2023.

Other Resources

National Standards Bodies in Developing Countries:

https://www.unido.org/sites/default/files/2008-10/fast_forward_0.pdf

Recommendations for achieving interoperable and shareable medical data in the USA:

<https://doi.org/10.1038/s43856-022-00148-x>

World Bank Checklist for a Sound Interoperability Approach, see Annex 1 on page 59 of :

<https://documents1.worldbank.org/curated/en/099550101092318102/pdf/P1694820242a9c041083900346bab0910eb.pdf>

ENISA's Procurement Guidelines for Cybersecurity in Hospitals, Industry Standards on Annex A, page 47 of: <https://www.enisa.europa.eu/publications/good-practices-for-the-security-of-healthcare-services>

List of relevant standards for the harmonization of the semantic and syntactic interoperability in the EHDS2, see page 6 of: <https://tehdas.eu/app/uploads/2022/02/tehdas-identification-of-relevant-standards-and-data-models-for-semantic-harmonization-2022-02-03.pdf>

European Interoperability Reference Architecture (EIRA):

<https://joinup.ec.europa.eu/collection/european-interoperability-reference-architecture-eira/about>

ETSI Technical Committee on eHealth: <https://www.etsi.org/committee/1396-ehealth>

Interoperable Europe Academy Catalogue of Educational Training Resources:

<https://joinup.ec.europa.eu/collection/digital-skills-public-sector/solution/interoperability-academy/catalogue-educational-training-resources>

Victoria (Australia) Department of Health Digital Health Standards and Guidelines:

<https://www.health.vic.gov.au/quality-safety-service/digital-health-standards-and-guidelines>

Digital Health Standards: <https://www.i-hd.eu/health-standards/>

Success stories: <https://www.i-hd.eu/health-standards/success-stories/>

United States Agency for Healthcare Research and Quality Standards:

<https://digital.ahrq.gov/standards-0>

United Kingdom National Health Service Standards and Collections :

<https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections>

United Kingdom Professional Record Standards Body: <https://theprsb.org/standards/>

Canada Ontario Digital Standards in Health: <https://www.ontariohealth.ca/system-planning/digital-standards>

Australian Medical Association 10 Minimum Standards Series:

Communication between Health Services and General Practitioners and Other Treating Doctors: <https://www.ama.com.au/articles/10-minimum-standards-communication-between-health-services-and-general-practitioners-and>

Medical Forms: <https://www.ama.com.au/article/10-minimum-standards-medical-forms>

Prescribing: <https://www.ama.com.au/media/new-standards-rule-out-pharmacist-prescribing>

Telemedicine: <https://www.ama.com.au/articles/10-minimum-standards-telemedicine>

Digital Health in General Practice: <https://www.ama.com.au/articles/10-minimum-standards-advancing-digital-health-general-practice>

eHealth Ontario EHR Interoperability Standards Selection Guide:

https://ehealthontario.on.ca/files/public/support/Standards/eHealth_Standards_Selection_Framework_en.pdf

India EHR Standards:

<https://main.mohfw.gov.in/sites/default/files/17739294021483341357.pdf>

Strengthening Uganda's Health System through Standardizing Digital Health:

<https://rif.mak.ac.ug/wp-content/uploads/2022/04/Mak-Health-Report.pdf>

South Africa National Health Act: National 2021 Normative Standards Framework for Interoperability in Digital Health:

https://www.gov.za/sites/default/files/gcis_document/202210/47337gon2667.pdf

United States Office of the National Coordinator (ONC) for Health Information Technology Standards Bulletin: <https://www.healthit.gov/topic/standards-technology/onc-standards-bulletin>

United States ONC Adopted Standards:

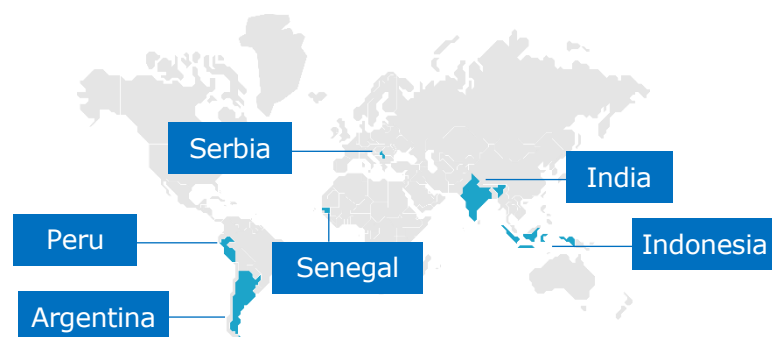
https://www.healthit.gov/sites/default/files/page/2022-07/Standards_And_Implementation_Specifications_Adopted_Under_Section_3004.pdf

Case studies, page 22 of: https://a78da35e-056b-4420-8e4f-41e3283327e3.usrfiles.com/ugd/55ae33_5af35824932c48d89287928244b60a8d.pdf

[41e3283327e3.usrfiles.com/ugd/55ae33_5af35824932c48d89287928244b60a8d.pdf](https://a78da35e-056b-4420-8e4f-41e3283327e3.usrfiles.com/ugd/55ae33_5af35824932c48d89287928244b60a8d.pdf)

services by means of electronic communications and information technologies (WHO 2022). Telemedicine is thus a component of telehealth.

Relevant World Bank Case Studies



Relevant External Case Studies

Uruguay's National Electronic Health Record System:

<https://publications.iadb.org/es/implementacion-de-la-historia-clinica-electronica-nacional-de-uruguay>

East African Community Regional Digital Health and Interoperability Assessments: Kenya:

<https://www.measureevaluation.org/resources/publications/tr-19-370.html>

East African Community Regional Digital Health and Interoperability Assessments: The United Republic of Tanzania: <https://www.measureevaluation.org/resources/publications/tr-19-385.html>

The Implementation of a National Health Information Exchange Platform in Israel:

<https://publications.iadb.org/publications/english/viewer/The-Implementation-of-a-National-Health-Information-Exchange-Platform-in-Israel.pdf>

Advancing Interoperability in Health Checklist

This checklist is for national and subnational levels; it can be printed as a stand-alone document.

Initial key questions for any project

- ☐ **Goal-orientation:** what is the overall goal and scale of the project?
- ☐ **Co-creation:** what stakeholders need to be involved to ensure success?

Assessment of current situation

- ☐ Characterize digital interoperability maturity levels (for example, using MEASURE Evaluation toolkit)
- ☐ Understand non-digital and digital interoperability in health using the WHO/ITU building blocks for electronic/digital health (including the enabling environment: Leadership and Governance; Strategy and Investment; Legislation, Policy and Compliance; Workforce; and Standards and Interoperability)
- ☐ Understand the information and communication technology environment: Infrastructure; and Services and Applications

Set the policy and organizational conditions

- ☐ Assign a national organization, or allow an existing organization (for example, a digital health agency, a health data authority, a ministerial department), governed by a multidisciplinary body with wide stakeholder representation, to have responsibility for interoperability in health
- ☐ Focus on cross-cutting and non-digital interoperability layers (interoperability governance, integrated service governance, legal, organizational, and cultural interoperability)
- ☐ Identify the National Standards Body and open a dialogue on interoperability in health
- ☐ Assess the development of a national/subnational framework for interoperability in health

Promote and implement digital interoperability

- ☐ Focus on digital interoperability (semantic, syntactic, and technical)
- ☐ Adopt an enterprise architecture approach that can support a variety of digital health interventions
- ☐ Create roadmaps for implementation, adoption, and enforcement tied to budgets and financing mechanisms

Monitor, evaluate, learn and continuously improve

- ☐ Put in place mechanisms for monitoring efforts to advance interoperability in health
- ☐ Identify indicators for assessing performance and impact, and for evaluating success, allowing the process to iterate

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Background on Implementation Know-How Briefs

What is an Implementation Know-How Brief and What is it For?

The World Bank's Digital-in-Health: Unlocking the Value for Everyone report calls for a new digital-in-health approach where digital technology and data are infused into every aspect of health systems management and health service delivery for better patient outcomes. The report proposes ten recommendations across three priority areas for governments to invest in: prioritize, connect and scale. The Implementation Know-How Briefs serve as practical, implementable extensions to the Digital Health Flagship report. The Implementation Know-How Briefs take a practical approach to discussing a topic with the aim of describing the topic, the key terms and technical considerations, guidance on how to start an operational engagement with clients on the topic, relevant checklists (if applicable), links and places to go for help.

The aim of Implementation Know-How Briefs is to give Task Teams enough information to figure out how a given topic fits into Health, Nutrition and Population (HNP) investments, and what are the right questions to ask. The aim is not to make Task Teams topic experts. The Implementation Know-How Briefs also tackle the dependencies between different topics.

Who is this Implementation Know-How Brief For?

The Implementation Know-How Briefs are focused on World Bank Task Teams, countries, and other organizations involved in implementation of Digital-in-Health activities and extend the discussion on the topics covered in the Digital Health Flagship report.

Who is Responsible for Implementation Know-How Briefs?

Digital Health Flagship Research Program: digitalinhealth@worldbank.org.



Annex 1

How are Standards Developed?

Standards are typically developed by standards developing organizations (SDOs), which can be national, regional, or international, but standards can also be developed by government agencies/departments, individual organizations (for example, businesses) or groups of organizations (for example, consortia). National SDOs are responsible for publishing, and possibly writing, national standards; representing their country in regional and international standard-setting fora; holding a reference library of national, regional, and international standards; selling copies of standards; and offering conformity assessment services such as accreditation, certification, or other commercial activities¹⁵.

Country SDOs can group together to form regional SDOs, such as the three European Standards Organizations (CEN, CENELEC and ETSI), The Pan American Standards Commission (COPANT), and the Pacific Area Standards Congress (PASC). The European Standards Organizations develop European Standards that can support European Union laws (known as Directives) or broader European public policies. Standards are mandatory when referenced in specific EU Directives. At a more global level, there are the three leading Standards Organizations: the IEC (International Electrotechnical Commission), the ISO (International Organization for Standardization) and the ITU (International Telecommunication Union). These three organizations collaborate on several initiatives, under the banner of the World Standards Cooperation.

A country's National Standards Body (NSB) is the national SDO selected by central government to represents the country at international and regional SDOs¹⁶. Besides representing its country at international and regional SDOs, the NSB can develop national standards, assist in the development of regulations, and provide training and education (ISO and UNIDO 2008). It is also responsible for the national standardization strategy – a policy roadmap to ensure that national strategic priorities are supported by relevant national and international standards (ISO 2020).

According to HIMSS, there are over 40 accredited SDOs in digital health, including the already mentioned HL7, SNOMED, and the Clinical Data Interchange Standards Consortium (CDISC)¹⁷. Different SDOs have different approaches and compositions, but very generally develop standards that meet specific needs, using a multi-expert-stakeholder, consensus-based process. As the ISO describes (see footnote for link), typically, the process of developing a new standard starts at the national level, with the government, an industry group, or a consumer group establishing the need for a new standard, and requesting that the national SDO take action. In response, the national SDO can develop a new standard, adopt an existing national standard

from another country, or adopt an international standard. The Institute of Electrical and Electronics Engineers (IEEE) process to develop standards illustrates the steps involved¹⁸:

- 1 Project initiation:** a formal request is submitted by an individual or entity (known as a Sponsoring Body) for review and evaluation
- 2 Working Group mobilization:** once the request is approved, the sponsor follows the SDO's rules and processes to recruit and assemble a collaborative team (IEEE refers to this team as a "Working Group") of volunteers to engage in active standards development
- 3 Standard drafting:** the team members engage in meetings, draft and review position pieces, create and review presentations, examine data and engage in active discussion and debate to resolve outstanding issues. All this leads to the gradual definition of each standard, which is compiled into a draft standard that may undergo multiple revisions
- 4 Standard balloting:** once a draft standard has been finalized, reviewed and approved by the Working Group, it's submitted to the sponsor who forms a balloting group consisting of persons interested in the standard. Group members will comment, discuss and then vote to approve the standard
- 5 Gaining final approval:** the balloted draft is submitted to the Review Committee and then to the Standards Board for approval. Once it's reviewed and accepted, the approved standard is published and made available for distribution and purchasing within a number of outlets, including through the SDO itself
- 6 Standard maintenance:** standards are "living documents" which may be iteratively modified, corrected, adjusted and/or updated based on market conditions and other factors

At the international level, the process also starts with a proposal for a new international standard typically submitted by a national SDO. At ISO, there are six stages in the development process: proposal, preparatory, committee, enquiry, approval, and publication. The process allows multiple stakeholders (from market players and experts to countries, especially developing countries) to contribute and build consensus.

As mentioned in IEEE's development process, standards are living documents. There will necessarily be revisions, corrections, and updates after publication and adoption. This is not only because the usefulness and value of a standard may only become clear after it is implemented,

but also due to the nature of health care and medical science (which are continually evolving), and due to new laws and regulations (for example, on emerging technologies like artificial intelligence and genomics) (MedTech Europe and COCIR 2021).

Examples of Prominent Standards in Health

The Digital Health Centre for Excellence (DICE) and the Healthcare Information and Management Systems Society (HIMSS) provide brief descriptions of some of the more prominent standards used to promote interoperability in health today (DICE 2022)¹⁹:

- **Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR)** is an open standard for exchanging healthcare information electronically. It provides standardized resources to form a basis for communicating the structure and meaning of clinical data. FHIR also provides standardization for application programming interfaces (APIs). FHIR provides several benefits and improvements including facilitating interoperable exchange with legacy standards, lower overhead, shorter learning curve, an ability to transmit only the necessary pieces of information, potential for patient mediated data, and a dynamic community of supporters and implementers
- **HL7 Version 3 Clinical Document Architecture (CDA)** is a standard that specifies the structure and semantic of clinical documents for the purpose of exchange between health care providers and patients. It defines a clinical document as having the following six characteristics: persistence, stewardship, potential for authentication, context, wholeness, and human readability
- **Integrating the Healthcare Enterprise (IHE) Profiles** provide a standard framework for sharing information needed by care providers and patients, across clinical workflows and information infrastructure. IHE Profiles organize and coordinate implementation of various communication standards
- **Digital Imaging and Communications in Medicine (DICOM)** is an international communication protocol and file format for exchanging medical images across systems and facilitates the development and expansion of picture archiving and communication systems
- **GS1 Standards** provide common language to identify, capture and share supply chain data and exchange metadata about medicinal products, devices, commodities, and vaccines
- **International Classification of Diseases and Related Health Problems 11th revision (ICD-11)** is a medical classification list developed by the WHO. It contains codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases
- **Logical Observation Identifiers Names and Codes (LOINC)** is a universal code system created by Regenstrief Institute. It is used for laboratory and clinical tests, measurements, and observations

- **Systematized Nomenclature of Medicine-Global Patient Set (SNOMED-GPS)** is the openly available subset of SNOMED Clinical Terms (SNOMED-CT), which is a clinical health terminology product from SNOMED International. It enables the consistent, processable representation of clinical content in electronic health records
- **European Union General Data Protection Regulation (GDPR)** outlines privacy and security regulations for all processing and storage of data relating to data subjects in the EU. This regulation extends to health information and any organization that may process or store data on these subjects, meaning it has extensive reach to many organizations worldwide and related to the sharing of data across organizations

Individual standards can be grouped together to form standards sets

The IHE initiative, for example, does not develop new standards. It bundles complementary base standards into profiles that are used to define a specific function or use case. Use cases are a way to describe or define a ‘user's view of interactions with (and within) the system”, including interactions between different entities²⁰. These bundles give standards users practical scenarios for how different base standards (for example, ICD-11) can be used to support business processes (in IHE’s case interoperable health information exchange). Other standards sets include the Joint Initiative Council’s Patient Summary Standards Set, the European Commission Recommendation on a European Electronic Health Record exchange format, or the Joint Action Towards the European Health Data Space (TEHDAS) (Joint Initiative Council 2018; European Commission 2019; TEHDAS 2022). The Joint Initiative Council is particularly interesting, as it brings together many key players in this space, for example, DICOM, GS1, HL7, ISO, LOINC, and SNOMED.

While there is no common and broadly used categorization of different types of standards, the figure below illustrates the (non-exhaustive) **range of standards that can contribute to interoperability in health**. There is overlap between different types of standards (for example, document standards depend on identifier standards, and medical device manufacturing standards may reference security standards). For example, adoption of and compliance with digital interoperability standards (for example, semantic, syntactic, and technical standards) is important, but **interoperability is also dependent on health workers adopting health care guidelines**. This enables digital health platforms and their subsequent interventions to not only be technically compliant, but also guideline-adherent in supporting patients, providers, or managers in care delivery²¹. See also “professional practice” and “quality assurance” below.

Non-Exhaustive Types of Standards Relevant to Digital Health, with Examples**IDENTIFICATION**

Biometrics (ISO 19794-6), Cards (ISO 7810), Barcodes (PDF417/QR code), Digital signatures (FIPS 186-4)

**IDENTIFIERS**

Patient identifiers (EMPI), Medical records (MRN), Nurses (NCSBN ID), Providers (NPI), Others (HL7 OID)

**DATA DISCOVERABILITY**

Genomics (Beacon), Clinical trials (ECRIN), Biological databases (FAIRsharing), population health (PHIRI)

**CONTENT/
STRUCTURE**

Clinical documents (HL7 CDA), Medical records (JIC PSSA), Discharge summary (HL7 DS), Continuity of Care (HL7 CCD)

**VOCABULARY/
TERMINOLOGY**

Diseases (ICD-10, ICD-11), Medicines (ATC), Laboratory (LOINC), Nursing (NANDA-I), Generic (SNOMED-CT)

**COMMUNICATION/
MESSAGING**

Imaging (DICOM), Medicines (ISO IDMP), Data quality (ISO 8000-110), Generic (HL7 FHIR)

**DATA
PRIVACY**

Rules and regulations (HIPAA Privacy Rule, GDPR), Governance guidelines (HISO 10064:2017)

**CYBER SECURITY**

Architecture (NIST NISTIR 7497), Rules (HIPAA Security Rule), Information security management (ISO 27799:2016), Ransomware (CCN-CERT IA-11/18)

**ARCHITECTURE**

Security (NIST NISTIR 7497), Information systems (CEN ENV12967), Service Architecture (ISO 12967-1:2020), Generic (TOGAF)

**MEDICAL DEVICES**

Risk management (IEC 80001-1:2010, ISO 14971), Quality management systems (ISO 13485:2016), Security (MDS2)

**INDUSTRIAL CONTROL
SYSTEMS**

Energy utility (ISO/IEC 27019:2017), Electrical installations (IEC 60364-7-710), Automation (ISA/IEC 62443)

**PROFESSIONAL
PRACTICE**

Telemedicine (AMA, Ontario Health), Prescribing (AMA), Online appointment booking (Ontario Health), Patient portals (Ontario Health)

**QUALITY ASSURANCE**

Digital mental health (NSQDMH), Digital health evidence (NICE ESF), National (NHSRC)

**SUPPLY-CHAIN
MANAGEMENT**

Contracts, schedules and pricing (HISO 10084.2:2021), Product identification (GHSC-PSM), Trade item identifiers (GS1 GTIN)

**PROCUREMENT**

Services (ISO/IEC 20000-1:2018), Software (IEC 62304:2006), Security (NIST-SP 800-66), Sustainability (ISO 20400:2017)

Note: this list is not exhaustive; there is overlap between categories (some standards fit into more than one category).

Increasingly, international organizations (such as the WHO and the World Bank) have pressed for the promotion and use of open standards. **Open standards are non-proprietary standards** that meet the following criteria (World Bank 2022):

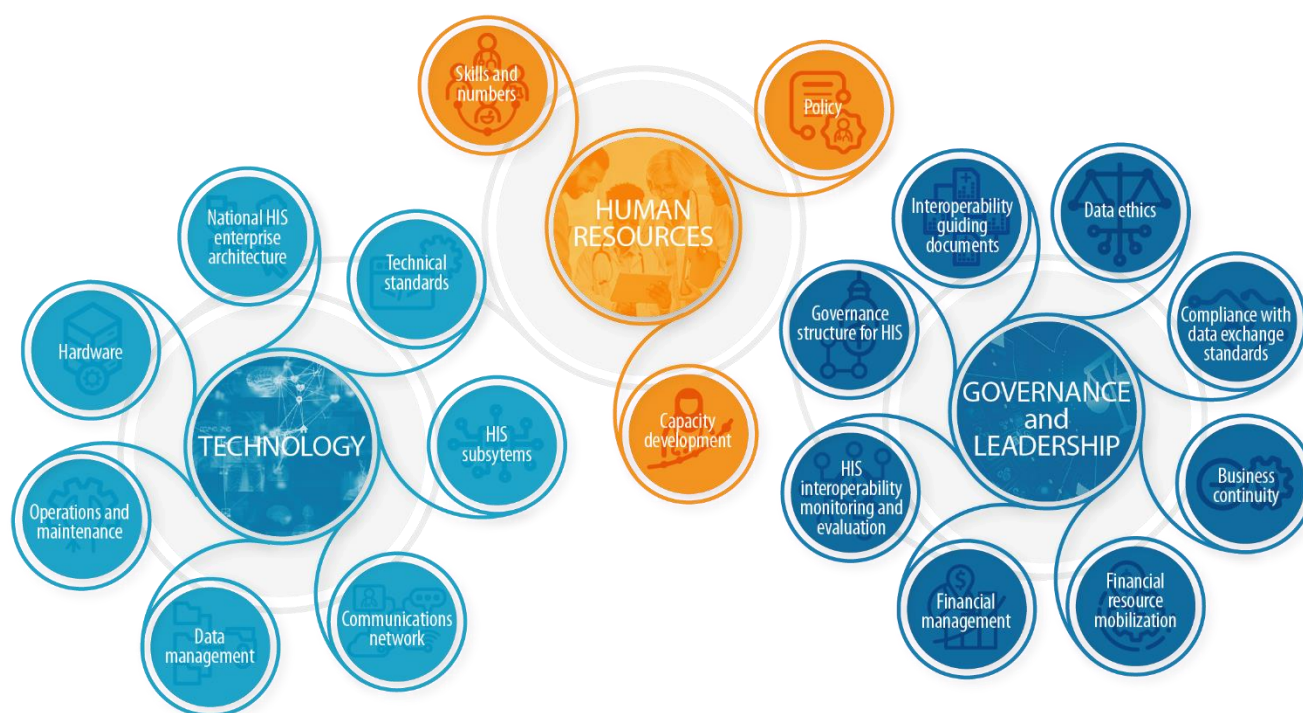
- Openness and transparency of the process to define standard's development, which entails no control by a single person or entity
- Standalone reusable platform, allowing for fast, simple, and multiple implementations.
- Limitless and freely supporting material for open standard creation and implementation (with some restrictions)
- Community-enforced and supported, approved through a co-creation and consensus.

According to the World Bank "highly mature GovTech countries are encouraged to share their code as open source and publish their standards as open standards, while low- and medium-level countries can especially benefit from already published open-source material and open standards to develop their interoperability initiatives".

Digital Interoperability Maturity Framework

Focusing on digital interoperability (semantic, syntactic, and technical), MEASURE Evaluation and the Digital Health and Interoperability Technical Working Group of the Health Data Collaborative have developed **a Health Information Systems Interoperability Maturity Toolkit** (published in 2017 and updated in 2019)²². The toolkit focuses specifically on low-resource settings, which often do not have the guidance and tools to assess their capacity to implement interoperable systems. The toolkit contains a maturity model, an assessment tool, a users' guide, and a literature review that was conducted as part of the toolkit's development. The toolkit was designed for ministries of health, their implementing partners, and other stakeholders to identify the key domains for interoperability and the required levels of maturity to achieve health information systems interoperability goals. There are other toolkits and frameworks though not focused on health (da Silva Serapião Leal, Guédria, and Panetto 2019).

Domains of the health information systems interoperability maturity model



Source: (MEASURE Evaluation 2017), also available in French.

WHO/ITU Building Blocks and Interoperability in Health

Regardless of what toolkits or frameworks are chosen to conduct the situational assessment of interoperability in health, **the WHO/ITU building blocks for electronic/digital health** are useful and can complement existing frameworks. The table below suggests some of the questions that Task Teams and client(s) should consider, for each of WHO/ITU's building blocks, in a specific interoperability project.

WHO/ITU'S building blocks and interoperability in health

Building block: Legislation, policy, and compliance

- Are there regulatory frameworks that govern how health information is collected, stored, accessed, and shared?
- Are there policies in place that support data protection and use of personal data?
- Are there policies that establish which interoperability standards are to be used and mechanisms for compliance?
- Are there legal mechanisms to ensure oversight for clinical safety and management of risks?
- Are there criteria for products and services established that include the requirement for interoperability with other systems? Is there an accreditation mechanism to quality assure and regulate the solutions available in the country?

Building block: Leadership and governance

- Is there a national interoperability framework? Is there a national standardization strategy?
- Are there plans to engage key stakeholders and keep them engaged throughout the process?
- Is there an overarching management, operations and support plan that will provide oversight and coordination to ensure reliability, availability, and sustainability of interoperable systems?
- Are there mechanisms to engage sectors outside of the health sector (for example, civil registration)?

Building block: Interoperability and standards

- Are there standards in place to promote digital interoperability (for example, content, terminology, messaging)?
- Are standards voluntary or mandatory? Is there certification of digital health products based on standards?
- Is there a plan to migrate or sunset an existing system so that they meet digital interoperability standards?

Building block: Workforce

- Is there adequate staffing? Are health care professionals under pressure from multiple demands on their time?
- Are there staff with the necessary skills, experience and knowledge required to design, build, operate, support, manage, and maintain interoperable systems?

Continued on next page...

WHO/ITU'S building blocks and interoperability in health (continued)

Building block: Strategy and investment

- Is there an overarching digital strategy to tie interoperability standards with health systems goals and challenges?
- Is there a funding mechanism for the implementation of interoperability in health, including through standards?

Building block: Infrastructure

- Is there physical computing infrastructure (for example, servers or cloud services) to support exchange of health data?
- Is current access to electricity and Internet connectivity appropriate for data exchange across systems?

Building block: Services and applications

- Are there registry services used to provide mutually exclusive and collectively exhaustive terminologies that are used throughout the digital health enterprise?
- Are there authentication services for secure transmission and delivery of health data?

Source: World Health Organization and Union 2012; DICE 2022.

Note: There is some overlap (for example, workforce issues are also often legislation and policy issues).

Digital Health Platform Deployment Approaches

The choice of Digital Health Platform deployment approach will depend on the context and existing information and communication technology systems, applications, and services, as well as available budget. The WHO highlights three types of deployment approaches: single system (centralized), two-way integration, and interoperable (as shown below).

Types of deployment approaches for organizing digital health platform components

Deployment approach	Definition	Advantages	Risks
Single system (centralized)	All components are deployed in a single DHP software deployment	<ul style="list-style-type: none"> End-to-end health process support within one system Low initial costs. Faster to deploy 	<ul style="list-style-type: none"> Single point of failure Difficult to scale, leading to higher costs as the DHP matures High degree of vendor lock-in
Two-Way Integration	Two discrete software systems are connected during deployment to form a DHP	<ul style="list-style-type: none"> Data shared between two systems Supports some scalability 	<ul style="list-style-type: none"> Costly over the long run Proprietary APIs and back-end database linkages impede change and encourage vendor lock-in Reduced stability in data exchange interfaces
Interoperable	Deployment can involve myriad number and types of software providing different DHP components, since the robust design relies on agreed- upon and validated data, interface, and workflow standards	<ul style="list-style-type: none"> Standards based, so highly scalable and extensible with a variety of systems and technologies Information exchange can cross sectors and organizations If one piece of software fails to deliver a component, it can be switched for another with minimal disruption to the DHP overall 	<ul style="list-style-type: none"> Higher initial costs Requires robust governance structures to implement data sharing effectively

Source: World Health Organization and International Telecommunication Union 2020.

Note: DHP – digital health platform; API – application programming interface.

Theory of Change

Telemedicine and Virtual Health Care Theory of Change



Gaps in use of health data and information and consequences

- People lack ways to take greater control of their health and communicate with their health care team
- Health care providers do not have access to consistent and timely information about their patients to promote appropriate and coordinated care
- Poor or no identification of at-risk and complex population groups, and no targeting delivery of appropriate treatments
- Limited data to assess health system performance and identify waste, inappropriate practice and inefficiency, and improve policy making, system governance and stewardship, including better funding and remuneration
- Potential to increase the propensity for dominant firms to emerge
- Limited or no data to inform effective responses to public health emergencies



Interoperability in Health

- Assess current state of interoperability in health, both digital and non-digital interoperability
- Have a national organization to oversee interoperability in health
- Set the right policy and organizational conditions (non-digital) for interoperability in health
- Promote and implement digital interoperability in health
- Establish clear governance for interoperability standards development and management
- Create roadmaps for implementation, tied to budgets and financing mechanisms
- Put in place mechanisms for monitoring performance and managing real-world interoperability



Outcomes

Shorter- and medium-term

- Improved health care quality and patient outcomes
- Improved health system and provider performance and management
- Improved care coordination and information sharing across all health care providers
- Improved communication and patient engagement
- Improved linkage and overall quality of health data and information
- Improved health monitoring, surveillance, and research
- Increased investments and donor funding
- Strengthened collaboration between client countries

Longer-term

- Enhanced capacity to develop and execute national digital health strategies



Expected longer-term impact

- Universal and equitable access to affordable, people-centered, and integrated quality care
- Good governance of health systems for sustainable financing and accountability for health outcomes
- Augmented service delivery value chain
- Reinvigorated essential public health functions

Examples of Barriers to Interoperability

The Global Digital Health Partnership (GDHP) published a white paper in 2020 on the topic of interoperability in health. The GDHP collected structured and illustrative information from GDHP participants to understand barriers to advancing interoperability. Country scores are shown below (Global Digital Health Partnership 2020).

Barriers to interoperability showing average scores and standard deviations

Country/Territory	Average Barrier	Lack of digital health system	Lack of accurate patient ID matching	Lack of infrastructure for secure transmission	Difficulty identifying and communicating w other entities	Existing standards are not adequate	Variability in choice of standards	Inconsistent implementation or constraints	Difficulty understanding what other providers meant	Two or more incompatible versions of standard	Lack of universal adoption of standards-based EHRs	Lack of EHR capability to take action on exchanged data	Poor usability and negative impact on workflows	Too much data is exchanged, meaningful data hard to find	Exchanged data missing what providers want	Data not available at point of care	Complex privacy and security challenges	Lack of trust in data quality	Inadequate or inconsistent approaches to patient consent	Regulations or variations in regulations increase burden	Information blocking	Difficulty managing coordinated collective action	Legislation lacks clarity	Increased costs due to interoperability	Economic incentives do not encourage data exchange	Unclear definition of use cases, low user engagement
Argentina	1.19	2	1	1	1	0	0	1	0	1	3	1					2	1	0	1	3	1	0	3	2	1
Australia	1.76	2	1	1	1	1	2	2	3	2	2	3	2	2	1	2	2	2	2	2	1	2	1	1	3	1
Austria	0.44	0	0	0	0	0	0	0	0	0	0	0	2	2	2	0	0	0	0	0	0	0	0	2	1	2
Brazil	2.00	3	3	3	3	2	2	2	1	0	3	3	1	2	1	3	3	2	1	1	0	3	2	2	2	2
Canada	1.92	1	3	1	2	0	3	1	2	2	1	2	2	2	2	2	3	2	2	3	2	3	2	2	1	2
Estonia	0.80	0	0	0	0	1	0	2	2	0	0	2	2	2	1	2	0	0	0	0	1	3	0	1	0	1
Hong Kong SAR	0.92	0	1	0	1	1	0	1	1	0	2	2	2	1	1	1	1	1	0	1	2	2	0	1	1	0
India	1.21	2	1	1	2	0	0	1	0	1	2	2	2	2	2	2	1	1	1	1	1	1	1	2		0
Indonesia	1.46	2	1	1	2	3	2	2	1	1	1	1	1	2	0	1	2	3	1	2	1	2		1	0	2
Italy	1.92	2	0	1	0	1	1	1	2	1	2	3	3	2	2	3	2	3	1	3	3	3	3	1	3	2
Japan	1.24	2	2	1	3	1	1	1	1	1	2	2	1	0	0	0	1	1	1	0	0	2	0	3	3	2
Kingdom of Saudi Arabia	0.68	1	0	0	0	2	0	0	0	0	2	3	2	1	2	0	0	0	0	0	0	0	0	2	2	0
The Netherlands	1.72	1	0	0	2	1	2	3	3	1	3	3	3	1	1	2	2	1	3	0	0	2	1	3	2	3
Poland	0.75	2	1	1	1	0	0	0	0	0	1						2	0	0	1	0	1	1	1	2	1
Portugal	1.96	3	2	0	2	2	3	3	3	2	2	2	2	0	0	1	3	2	3	3	0	3	3	2	0	3
Republic of Korea	0.88	1	0	0	0	1	1	1	2	0	2	2	1	1	1	0	1	1	0	0	1	1	0	2	2	1
Singapore	0.84	1	1	1	1	1	0	1	0	0	1	0	1	0	1	0	1	1	0	1	2	2	0	2	2	1
Sweden	2.20	0	0	0	3	0	3	3	3	3	2	3	3	1	2	3	2	2	3	3	3	3	3	2	3	2
Switzerland	1.24	3	2	0	2	0	1	2	1	1	2	3	2	0	0	3	0	1	1	0	1	2	0	2	1	1
United Kingdom	1.16	1	0	0	1	1	2	1	2	1	2	2	1	1	1	2	2	1	1	0	1	2	0	2	1	1
Uruguay	0.64	0	0	0	0	1	0	0	1	0	1	1	2	1	1	1	0	2	0	0	1	1	0	2	1	0
United States	2.00	0	3	1	3	1	1	2	2	1	1	3	3	3	2	3	3	2	2	3	3	2	1	2	1	2
Average	1.32	1.32	1.00	0.59	1.36	0.91	1.09	1.36	1.36	0.82	1.68	2.05	1.90	1.30	1.15	1.55	1.50	1.32	1.00	1.14	1.18	1.86	0.86	1.86	1.57	1.36
Std Deviation		1.02	1.04	0.72	1.07	0.79	1.08	0.93	1.07	0.83	0.82	0.95	0.70	0.84	0.73	1.12	1.03	0.87	1.04	1.18	1.07	0.92	1.08	0.62	0.95	0.88

Key: Yellow = areas of low variability

Red = areas of high variability

Grey = no response provided

Orange = tier 1 barriers

Source: Global Digital Health Partnership 2020.

Notes

- ¹ Online sources include the United Kingdom's National Health Service's Clinical Information Standards (available from <https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/nhs-digital-data-and-technology-standards/clinical-information-standards>), the Digital Health Europe's Digital Health Standards (available from <https://www.i-hd.eu/health-standards/>), the Standards Council of Canada (available from <https://www.scc.ca/en/types-standards>), and the International Organization for Standardization (available from <https://www.iso.org/benefits-of-standards.html>).
- ² See HIMSS webpage on interoperability in health available from <https://www.himss.org/resources/interoperability-healthcare>.
- ³ See Standards Council of Canada (available from <https://www.scc.ca/en/types-standards>), and the International Organization for Standardization (available from https://www.iso.org/sites/ConsumersStandards/1_standards.html).
- ⁴ See the International Organization for Standardization available from https://www.iso.org/sites/ConsumersStandards/1_standards.html.
- ⁵ See the Principles for Digital Development available from <https://digitalprinciples.org/principles/>; the World Bank Group endorsed these principles in 2016.
- ⁶ In 2021, 20 OECD countries reported having a national organization responsible for setting national standards for clinical terminology in electronic health records and for data exchange (OECD 2022).
- ⁷ MEASURE Evaluation's Health Information Systems Interoperability Maturity Toolkit can be accessed from <https://www.measureevaluation.org/resources/tools/health-information-systems-interoperability-toolkit.html>.
- ⁸ See eHealth Ontario's electronic health record standards available from <https://ehealthontario.on.ca/en/it-professionals/standards>
- ⁹ See Health Data Governance Summit pre-read on the health data landscape available from https://cdn.who.int/media/docs/default-source/world-health-data-platform/events/health-data-governance-summit/preread-1-who-data-governance-summit_health-data-landscape.pdf.
- ¹⁰ See Common Assessment Method for Standards and Specifications (CAMSS) available from <https://joinup.ec.europa.eu/collection/common-assessment-method-standards-and-specifications-camss/about>.
- ¹¹ See HIMSS webpage on interoperability in health (available from <https://www.himss.org/resources/interoperability-healthcare>).
- ¹² See standards lifecycle available from <https://www.tewhatauora.govt.nz/our-health-system/digital-health/data-and-digital-standards/standards-lifecycle/>.

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- ¹³ See HIMSS webpage on interoperability in health available from <https://www.himss.org/resources/interoperability-healthcare>.
 - ¹⁴ See HIMSS webpage on interoperability in health available from <https://www.himss.org/resources/interoperability-healthcare>.
 - ¹⁵ See the International Organization for Standardization available from https://www.iso.org/sites/ConsumersStandards/1_standards.html.
 - ¹⁶ See, for example, the members of the International Standards Organization available from <https://www.iso.org/members.html>.
 - ¹⁷ See HIMSS webpage on interoperability in health available from <https://www.himss.org/resources/interoperability-healthcare>.
 - ¹⁸ See IEEE's webpage on Understanding How Technical Standards are Made & Maintained available from <https://innovationatwork.ieee.org/understanding-how-technical-standards-are-made-maintained/>.
 - ¹⁹ See also HIMSS webpage on interoperability in health available from <https://www.himss.org/resources/interoperability-healthcare>.
 - ²⁰ See the International Organization for Standardization webpage available from <https://www.iso.org/obp/ui/#iso:std:iso:tr:25102:ed-1:v1:en>.
 - ²¹ See WHO's Smart Guidelines (available from <https://www.who.int/teams/digital-health-and-innovation/smart-guidelines>), IHE computable care guidelines (available from https://wiki.ihe.net/index.php/Computable_Care_Guidelines), and (Republic of Uganda 2021).
 - ²² MEASURE Evaluation's Health Information Systems Interoperability Maturity Toolkit can be accessed from <https://www.measureevaluation.org/resources/tools/health-information-systems-interoperability-toolkit.html>.

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