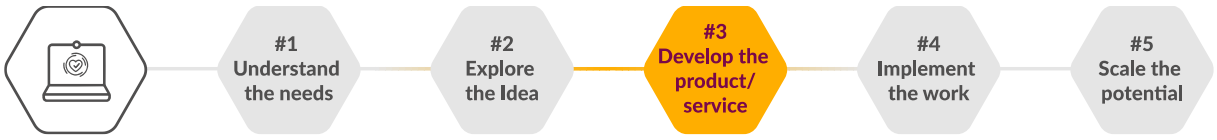


3.1 Test and validate the concept
3.2 Develop the product/service

3.3 Decide on healthcare integration strategies

3.4 Set up an implementation plan

What?

Health care Integration is the process of joining distinct systems in such a way that they appear as being a whole in a particular perspective. Integration can also be defined as the capacity of natively independent systems to interact properly without having to deeply modify their own structure and behaviour.

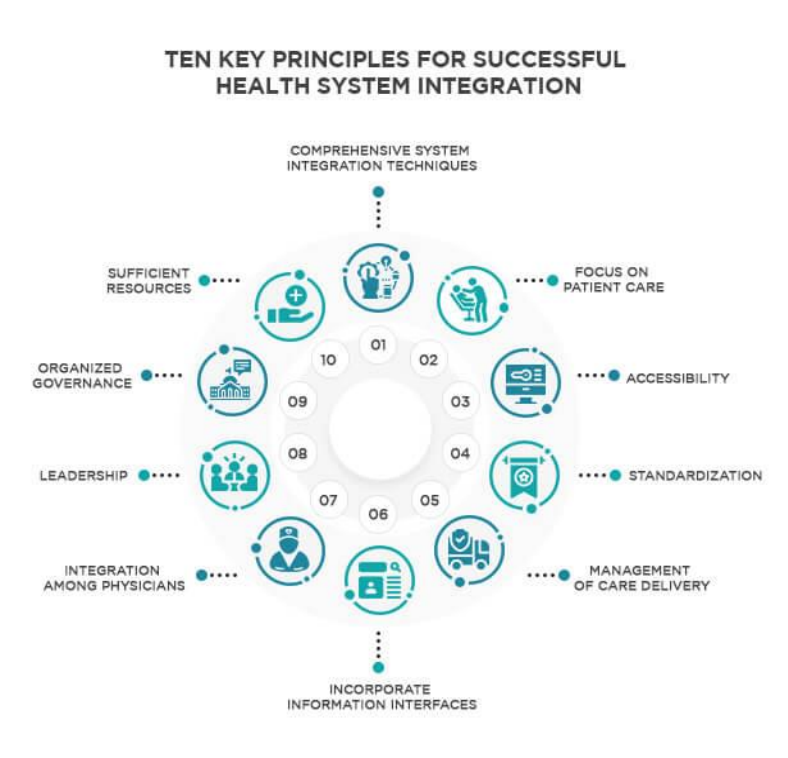
Why?

One obstacle for efficient use of digital tools and ehealth systems is that they-often are fragmented and operating in isolation or silos which does not favour data sharing, access and use since there is a communication gap between the systems. Thus the main purpose of integrating health systems is to provide seamless and secure services through making them more accessible, easy to understand and to use with an overall goal of attaining better patient health through enhancing the care provided by hospitals and other health institutions.

How?

Successful health system integration can be attained using different avenues and strategies some of which include comprehensive system integration techniques like interoperability and standardisation, focus on patient care, accessibility, leadership, organised governance, integration among physicians and sufficient resources among others.

In this tool we are going to focus on interoperability standards and frameworks because they contain and represent the major issues around successful health system integration.



Key principles for successful health system integration

Content

Interoperability

Interoperability is the ability of different information systems, devices and applications to access, exchange, integrate and cooperatively use data within and across organisations globally in a timely, secure and seamless manner in order to provide optimal health care for all. This is done with the help of health data exchange architectures, frameworks, application interfaces and standards, which enable secure data access and sharing with all the relevant stakeholders, including the individuals. For effective integration, you need to consider four levels of interoperability namely; *foundational, structural, semantic* and *organisational*.

The **foundational level** ensures that 2 systems or applications are able to securely communicate data and to receive data from each other through health information exchange (HIE) and data sharing. The goal of HIE is to facilitate access to and retrieval of data in a safe, timely, efficient and effective manner for use by the relevant stakeholders For example, it is possible to share clinical information among disparate health care information systems without changing the meaning of the information being shared.

The structural level deals with the format, syntax and organisation of data exchange. This is concerned with how the relevant data is going to be shared.

The **semantic level** is concerned with standard definitions of data elements mainly from publicly available value sets and terminologies to provide shared understanding and meaning to the user.

The organisational level handles issues like governance, policy, social, legal and organisational considerations that support or facilitate secure, seamless and timely communication and use of data both within and between organisations, entities and individuals to enable shared consent, trust and integrated end user processes.

Important to note is that interoperability is driven by standards, and in the proceeding section we introduce the different types of standards and the roles they play in ensuring health system integration. The standards we talk about in this section cover the foundational, structural and semantic levels, also known as the technical levels and the organisational level (non technical).

Interoperability Standards

What?

Standards provide a common language and a common set of expectations that enable interoperability between systems and/or devices. Standards consist of methods, protocols, terminologies and specifications for the collection, exchange, storage and retrieval of information such as medical records, medications, radiological images, payment and reimbursement, medical devices, monitoring systems and administrative systems. At the most basic level, data standards define what to collect, how to present the collected data elements by designating data types or terminologies and how to encode the data for transmission (Braa and Sahay, 2012).

Why?

Standards enable the different entities and stakeholders such as clinicians, labs, pharmacies, hospitals and patients to seamlessly share data.

Description

There are five main standards created by the Standards Development Organization (SDO) that are widely used across the various healthcare organizations. These include;

- Terminology/vocabulary standards,
- Content standards,
- Data exchange or transport standards, and
- Privacy and security standards.
- Identifier standards

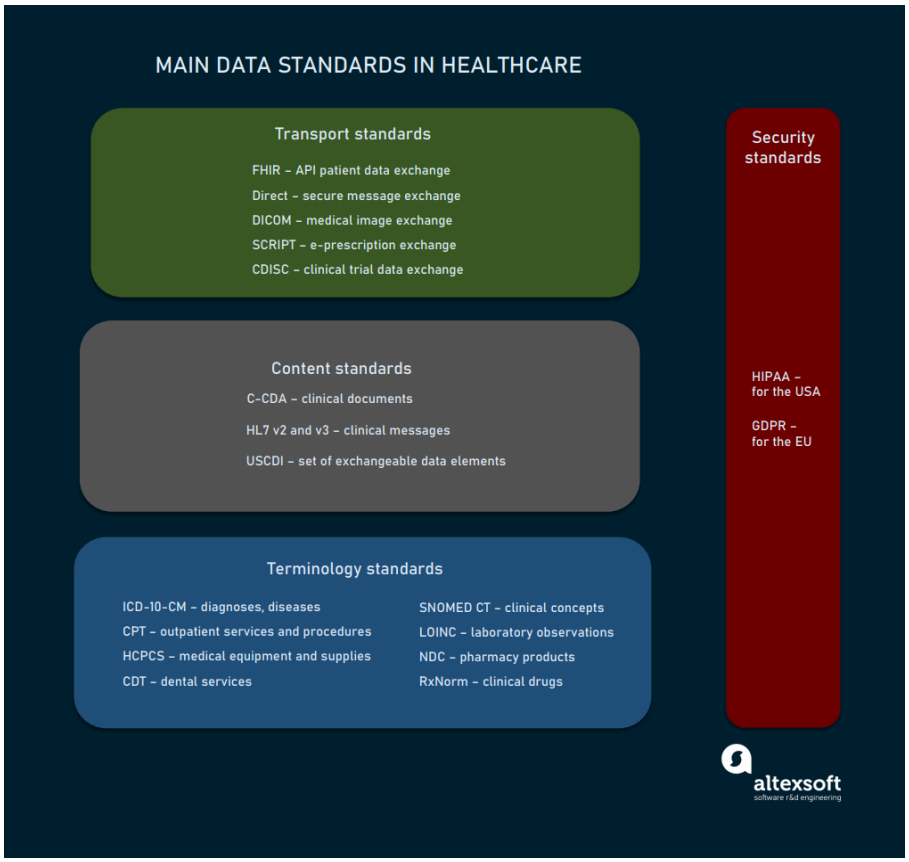


Figure 5: Main data standards in health care (https://www.altexsoft.com/blog/data-standards-healthcare/)

Vocabulary/Terminology standards

These standards aim at representing health concepts between a sender and a receiver of information in an ambiguous manner by using structured vocabularies, terminologies, code sets and classification systems. Much as health data may be exchanged without terminology standards, there is no guaranteeing that all the involved parties will be able to understand and use it. For example, suppose two systems call the same disease by a different name, or the same name being given to different elements. This would lead to miscommunication, and hence misguided decision making due to a lack of content clarity.

Figure 11: Key healthcare coding systems (altexsoft, 2020)

For additional codes, their descriptions and functionalities, refer to the list below in (https://www.himss.org/resources/interoperability-healthcare)

- Current Procedural Terminology (CPT®): Used to bill outpatient and office procedures.
- Healthcare Common Procedure Coding System: Used for Medicare reimbursement and is based on CPT. .
- ICD-10 and ICD-11: Is a medical classification list by the World Health Organization (WHO) and 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®): Represent the codes used to identify health measurements, observations and documents, for example in laboratory and clinical tests, measurements and observations.
- National Drug Code (NDC): Provides a list of all drugs manufactured, prepared, propagated, compounded or processed for commercial distribution. Maintained by the U.S. Food and Drug Administration.
- RadLex: A unified language of radiology terms for standardized and is a good supplement to standards like SNOMED-Clinical Terms and DICOM.
- RxNorm: Focuses on names for clinical drugs and is commonly used in pharmacy management and drug interaction software.
- Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT): Offers terminology that is used to represent content in electronic health records (EHR). They are the responses to the LOINC "question" code.

- The Centers for Disease Control and Prevention (CDC) provide a number of code sets for vaccines (Vaccines Administered (CVX)) and manufacturers (Manufacturers of Vaccines (MVX)). These codes can be used in immunization messages.
- The Unified Code for Units of Measure: A code system intended to include all units of measures used in international science, engineering and business.

Content standards

Content or document standards support the structure of electronic documents and types of data they must contain when exchanging information. They ensure that medical data is properly organized and represented in a clear and easy to understand form and in addition define the common sets of data for specific message types. Examples of content standards include:

- HL7's Version 2.x (V2): It allows the exchange of clinical data between both centralized patient care and distributed systems.
- HL7 Version 3 Clinical Document Architecture (CDA®): Specifies the structure and semantics of "clinical documents" during information exchange between healthcare providers and patients.
- The Consolidated Clinical Document Architecture (C-CDA) is a framework used to create electronic clinical documents in the US through capturing, storing and displaying of both structured and unstructured information. It specifies how to structure medical records and how to encode data elements for exchange.
- US Core Data for Interoperability or USCDI is a mandatory set of content pieces hospitals must share on a patient's request via APIs. These include but are not limited to; patient demographics, health concerns, medications, procedures, and more. The USCDI also identifies terminology systems to be used and some of the recommended code systems include; LOINC, SNOMED CT, and RxNorm. Below is an example of the latest USCDI (version 2).

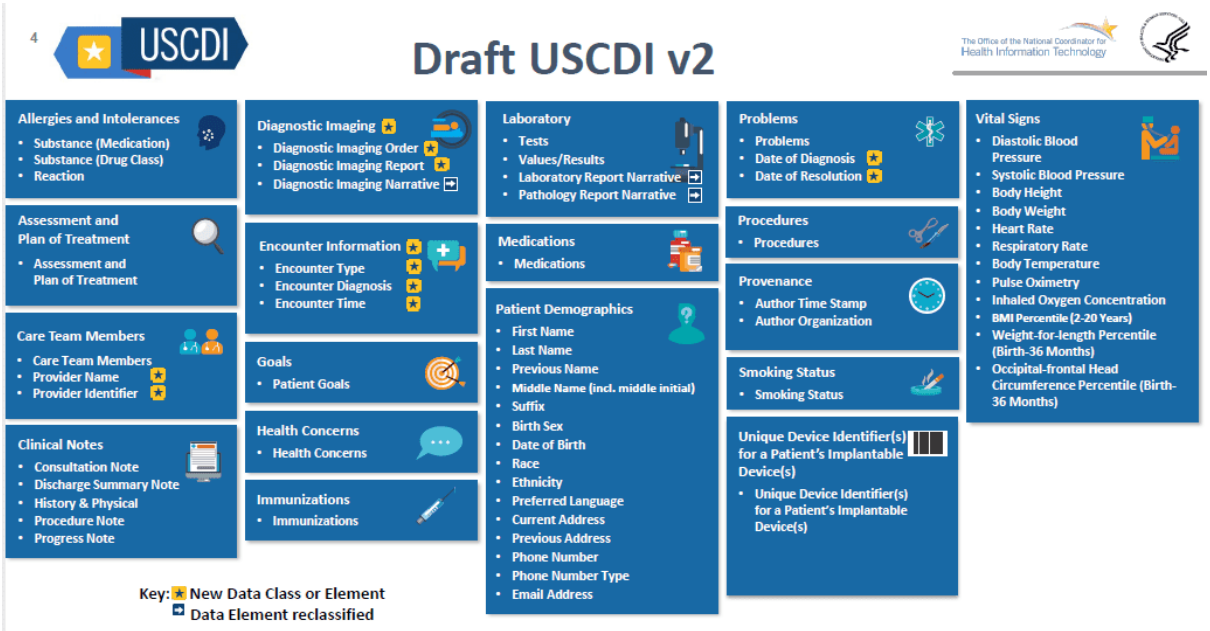


Figure : Electronically accessible data elements and classes specified by the 2nd version of USCDI (John Lynn, 2021)

Transport standards

Transport standards facilitate data exchange between different health systems. They define what formats, document architecture, data elements, methods, and APIs to use for achieving interoperability. Some of these transport standards include:

- The Digital Imaging and Communications in Medicine (DICOM) for transmitting medical images across systems and facilitates the development and expansion of picture archiving and communication systems.
- SCRIPT for electronic prescribing such as exchanging electronic prescriptions and related data between care providers, pharmacies, and health plans.
- Clinical Data Interchange Standards Consortium or CDISC standards are used for medical research data exchange eg exchange of clinical trial data between pharma companies and researchers.
- Direct Standard : Defines a set of standards and protocols to allow participants to send authenticated, encrypted health information directly to known, trusted recipients over the internet.
- Fast Healthcare Interoperability Resources (FHIR®): An HL7 standard for exchanging healthcare information electronically through the use of "resources," which describe exchangeable health data formats and elements and standardization for application programming interfaces (APIs)

Privacy and security standards

Privacy and security standards establish administrative, physical and technical rules and actions to protect sensitive health data from misuse, unauthorized access, or disclosure. Both individuals and organisations have a right to determine who collects and uses their personal health information and for what purpose. Examples of standards are as below;

- Health Insurance Portability and Accountability Act (HIPAA) for health data across the US outlines the privacy and security standards for medical information. HIPAA Privacy Rule applies to individual medical records and other personal health information It sets limits on the use and sharing of patient data for health plans, healthcare providers, and other players. It further empowers patients to freely access their medical records and request corrections to them. HIPAA Security Rule defines what electronic health information must be protected and what technologies, policies, and procedures must be in place to ensure the appropriate level of security.
- The General Data Protection Regulation (GDPR) for health data across the EU

  These standards/guidelines emphasize that healthcare organizations must appoint a Data Protection Officer (DPO); conduct a Data Protection Impact Assessment (DPIA) which entails evaluating data protection risks; implementing a cybersecurity strategy; and reporting data breaches within 72 hours. Similar to HIPAA standards, GDPR also gives patients the right to access their personal data.

Identifier Standards

Identifier standards are used to uniquely identify patients or providers. Examples include;

- Enterprise Master Patient Index (EMPI): A data registry used across a healthcare organization to maintain consistent and accurate data on the patients treated and managed within its departments.
- Medical Record Number (MRN): An organization specific code used as a systematic documentation of a patient's history and care during a hospital stay.
- National Council of State Boards of Nursing ID (NCSBN ID): A unique identifier automatically generated for each registered nurse and licensed practical/vocational nurse, freely available via the Nursys database and maintained by NCSBN.

  - National Provider ID (NPI): A unique 10-digit number for a healthcare provider to create a standard identification. These NPIs are included in the free NPI Registry.
  - Object ID (OID): A globally unique ISO identifier and a preferred scheme for unique identifiers in HL7.
- In Sweden, a Bank ID paired with the owner's personal ID number is used as an identifier app and is used to access all services including health care services.

Public policy and Government efforts

In addition to the technical requirements, interoperability also considers policy and organisational issues that must be addressed to ensure the successful exchange of data. Governments play a very big role in achieving interoperability by setting up policies and regulations. These public policies have the potential to support frameworks for trusted exchange, aligning and education of stakeholders on the existing and emerging standards and facilitating stakeholder participation in achieving secure exchange of data. Some of the public policies currently being implemented worldwide include;

- The draft Trusted Exchange Framework and Common Agreement which includes policies, procedures and technical standards that provide single access to electronic health information regardless of the developer, health information exchange, or where a patient's records are located (USA).
- The U.S. Core Data for Interoperability is a "standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange." (USA)
- The ONC Interoperability and Information Blocking Final Regulation which is focused on advancing interoperable exchange; supporting the access, exchange and use of electronic health information; and addressing occurrences of information blocking (USA)
- https://www.imy.se/en/organisations/data-protection/data-protection-within-different-areas/vard/vardgivares-skydd-for-patientuppgifter/ (Patient data protection by the Swedish Authority for Privacy Protection)
- https://ict.go.ug/wp-content/uploads/2019/03/Data-Protection-and-Privacy-Act-2019.pdf (Uganda)
- https://www.pdpo.go.ug/home (Data protection and privacy portal launched in Uganda on 1st June 2022)
- The Global Digital Health Partnership (GDHP), a collaboration of over 40 governments and territories, government agencies and the World Health Organization, formed to support the effective implementation of digital health services. A GDHP report outlines a variety of government efforts from 15 participating countries.
- In Europe, the EU EHR Exchange Format developed the EU's eHealth Network to support the digital transformation of health and care in the EU by seeking to unlock the flow of health data across borders, and support implementation of the Cross-Border Health Care Directive. http://norden.diva-portal.org/smash/get/diva2:1340369/FULLTEXT01.pdf (Nordic countries)
- The EU MDR regulations intended to improve the safety and performance of medical devices in Europe and intend to provide a high level of protection for the health of patients and users of these medical devices. https://www.medical.saint-gobain.com/about-us/blog/eu-mdr-what-it-and-why-it-necessary

For more and detailed information on the standards and policy efforts, please refer to
https://www.altexsoft.com/blog/data-standards-healthcare/
https://www.himss.org/resources/interoperability-healthcare#Part6

Interoperability frameworks

An interoperability framework comprises a set of standards and guidelines which describe the way organisations or stakeholders have agreed or should agree to interact with each other. We discuss the different interoperability frameworks below and how some of the standards and guidelines mentioned earlier are incorporated in the frameworks. In this section we target researchers and software developers who can make use of these frameworks when developing and deploying health information systems. In addition healthcare implementers and decision makers can adopt segments or parts of the contents in these frameworks to smoothen the integration process. The choice of framework to use depends on the kind of health information systems involved and nature of information exchange required.

eHealth European Interoperability Framework (eHeath EIF) (European Commission, 2010)

It is based on the generic European Interoperability Framework (EIF) (European Commission, 2010) to the domain of eHealth with an aim of providing a set of recommendations and specifications to connect eHealth systems. It identifies four levels of interoperability namely: legal, organizational, semantic, and technical. An overview of these different EIF concepts is given in figure 2.

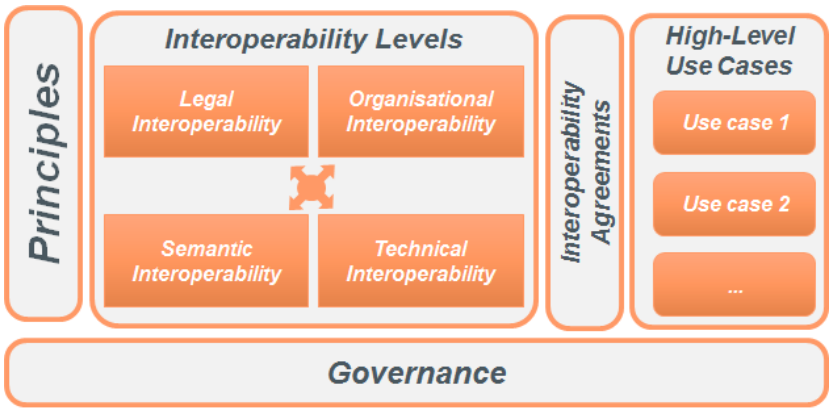


Figure 3: Structure of the eHealth EIF (European Commission, 2010)

- Under legal interoperability you must ensure that the legal procedures concerning exchanged data are fulfilled.
- With organizational interoperability ensure that the different organizations with whom you are working achieve a mutual and beneficial goal that was previously agreed upon, yours inclusive.
- Semantic interoperability aims at ensuring that the exchanged data/information is preserved and understood by all the parties involved.
- Technical interoperability considers the technical issues involved in linking computer systems and services.

Interoperability governance is concerned with the ownership, definition, development, maintenance, monitoring, promoting and implementing of interoperability frameworks where multiple organizations are working together to provide (public) services. For more details, please see (European Commission, 2013).

The Health Information Systems Interoperability Framework (ASIP Santé-PRAS, 2010)

The Health Information System (HIS) Interoperability Framework is a reference framework created by ASIP Santé (Agence nationale des Systèmes d'Information Partagés de Santé). The framework was intended to support the development of services that are needed for the electronic sharing of personal health information and to create interoperability conditions that meet privacy and security requirements between HIS systems. It does this by specifying standards and how these can be implemented to facilitate interoperable HIS.

The framework is divided into modules which are distributed across 3 interoperability layers as defined below;

- Content layer (semantic and syntactic content)- Specification of exchanged or shared content based on structure and vocabularies
- Service layer : Specification of content sharing or exchange services, their rules and usage parameter
- Transport layer: Specification of exchange protocols used by services.

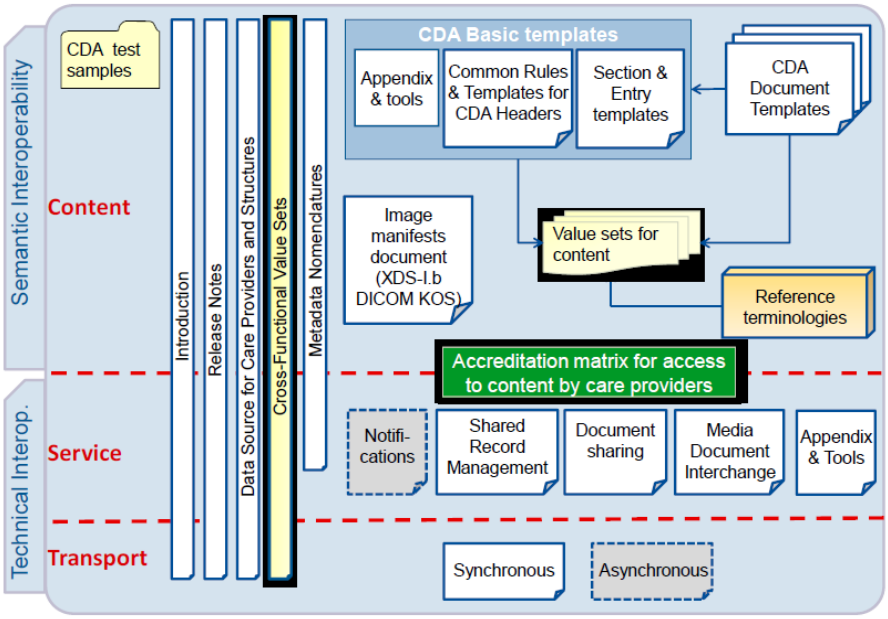


Figure: Organization of the HIS Interoperability, (ASIP Santé-PRAS, 2010)

eHealth Interoperability Framework (eHealth IF) (NEHTA, 2017)

This framework was developed by the National E-Health Transition Authority (NEHTA) initiatives in Australia. It defines three levels of interoperability across health organizations namely;

- The Organizational layer which provides a shared policy and process framework across the eHealth interoperability agenda covering each NEHTA initiative. It includes the Business Processes, standards plan, security policies and Privacy.
- The Information layer which provides shared building blocks for semantic (information) interchange/exchange. This includes foundation components, value domains, structures, common assemblies, relationships, and metadata.
- The Technical layer is concerned with the connectivity of systems for information exchange and ser-vice use.

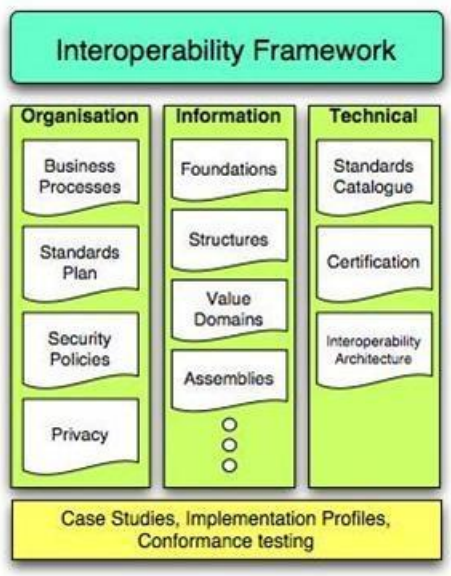


Figure 5: eHealth Interoperability Framework, (NEHTA, 2017)

Personal Health System Framework (European Commission, 2011)

Personal Health Systems (PHS) are used to seamlessly provide quality controlled, and personalized health services to individuals regardless of location. These may be wearable or portable devices some of which may perform intelligent processing services based on the data collected from an individual and expert biomedical knowledge that can be used to derive insights. These insights can be communicated to an individual.

The PHS Interoperability Framework (PHS IF) can be divided into two smaller frameworks namely:

- The technical & implementation framework- This entails standards, profiles and guidelines for their implementation based on elaborated business use cases, identification & authentication mechanisms, security protocols, testing and certification, etc.,
- The institutional / organizational framework which consists of policy issues (e.g.governance, reimbursement), legal and regulatory aspects such as data protection, liability, etc. (European Commission, 2011)

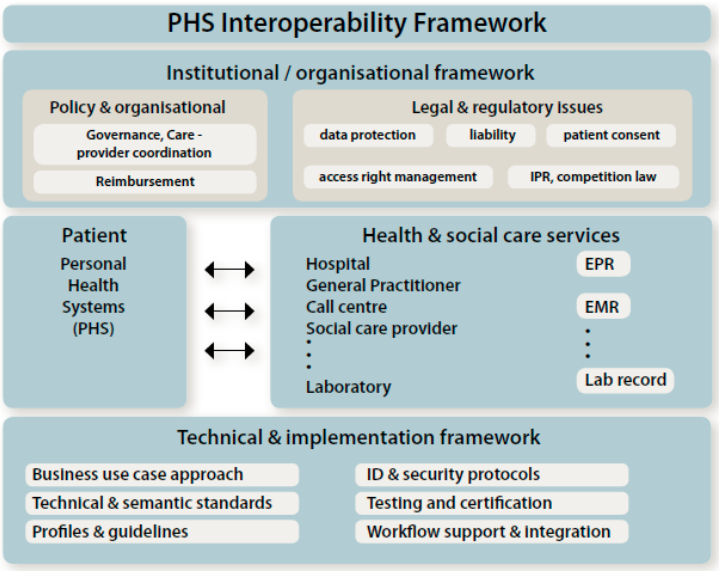


Figure 6: PHS Interoperability framework, (European Commission, 2011)

Resources/Sources:

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- NEHTA. Interoperability Framework, Version 2.0, August 17 2017.

Links to additional data protection acts policies and infrastructures globally can be found here:
Key principles for successful health system integration (https://www.osplabs.com/insights/how-to-build-integrated-health-solutions-to-boost-efficiency/)
https://www.imy.se/en/organisations/data-protection/data-protection-within-different-areas/vard/vardgivares-skydd-for-patientuppgifter/
https://www.altexsoft.com/blog/data-standards-healthcare/
https://www.himss.org/resources/interoperability-healthcare#Part6

← 3.2 Develop the product/service
3.4 Set up an implementation plan →