

PD ISO/TR 14639-2:2014



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Health informatics — Capacity-based eHealth architecture roadmap

Part 2: Architectural components
and maturity model

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National foreword

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TECHNICAL REPORT

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14639-2

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Health informatics — Capacity-based eHealth architecture roadmap —

Part 2: Architectural components and maturity model

*Informatique de santé — Feuille de route de l'architecture de santé
électronique fondée sur la capacité —*

Partie 2: Composants architecturaux et modèle de maturité



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

ISO/TR 14639 consists of the following parts, under the general title *Health informatics — Capacity-based eHealth architecture roadmap*:

- *Part 1: Overview of national eHealth initiatives*
- *Part 2: Architectural components and maturity model*

Introduction

ISO/TC 215 has identified that there is an urgent need to provide International Standards for health information architectures that includes requirements tailored also to low- and middle-income countries with relatively immature resources available. A Public Health Task Force of international experts, established by TC 215, has developed a report outlining the challenges these countries face and some of the relevant standardization strategies.

This part of ISO/TR 14639 provides a guide to best practice business requirements and principles for planning the use of information and communications technology (ICT) to support the development, coordination, and delivery of healthcare services by countries and subordinate health authorities within a country.

One of the activities motivating this work originates from a meeting in March 2010, in Bellagio, Italy to explore how the “digital divide” between high-income and low-income countries could be addressed.^[10]

The following observations were noted.

- a) There is a surge of interest in the development of eHealth infostructure to support effective Health Information Systems (HIS) in low-income countries, including responding to disease outbreaks, monitoring the health status of the population, and improving both public and individual health.
- b) Health informatics International Standards help countries to make the proper decisions regarding their eHealth architecture such that they can strengthen their health systems. HIS architectures that are non-proprietary and based on International Standards are likely to be more robust and future-proof.
- c) The use of health informatics International Standards in low-income countries is hampered due to lack of knowledge and awareness about appropriate standards, affordable access to standards and implementation guides, and little participation in Standards Development Organization (SDO) activities due to little or no funding to support such engagement.
- d) Existing international health informatics International Standards insufficiently address the needs of low-income countries (LICs) for developing their monitoring, public health, and patient care systems. An example of this is mobile computing and the use of SMS for transmitting patient information, reminders, and alerts. Thus, the participation of LICs in the International Standards development process is essential.
- e) Participation in ISO activities requires a national standards organization or government department as an official member of ISO.
- f) Development of International Standards has a cost. A significant amount of money and time needs to be invested in preparation of documents, commenting on proposals, and participation in SDO meetings and for adopting, adapting, and localization of standards. These costs represent a genuine barrier to the participation of low-income countries.
- g) Access to International Standards also comes with a cost that is often prohibitive for people and organizations in low-income countries.
- h) There is recognition that the business model of some SDOs is based on the sale of International Standards to support the standards development process and operating expenses.
- i) HIS strengthening can be promoted by using commonly shared International Standards to carry out Monitoring and Evaluation (M & E) activities for government bodies, international organizations, donors, and other interested parties.
- j) There are duplications and overlaps in health informatics International Standards across multiple SDOs. Low-income countries require a single set of usable International Standards based on the work of ISO/TC 215, HL7, and CEN/TC 251 Joint Initiative Council (JIC) to harmonize International

Standards and facilitate the global, international adoption, and adaption of organizational and regional standards based on the ISO standards process.

- k) Promotion of International Standards worldwide is consistent with the ISO mission yet barriers exist to the achievement of this objective.

While not all of these observations are addressed within the scope of this Technical Report, the report is an attempt to respond to some of these observations, providing a robust framework for low-income countries for their eHealth architecture planning and health system development. The other items are intended to be addressed in due course.

This part of ISO/TR 14639 examines various activities and associated criteria for the effective use of information and communication technology (ICT) in support of health service delivery, planning, and coordination. It aims to provide relevant guidance on uses of information, based on model criteria by which development of eHealth capability can be planned and progress toward its mature use can be assessed.

In preparing this part of ISO/TR 14639, the original aim was to provide guidance for developing and emerging countries and for the many international groups that conduct health programs in the developing and emerging world. As the work proceeded, it became clear that the work is more widely applicable to all health services and that there are potential lessons for all as they examine the way in which information is produced, managed, and used in various aspects of their work. The identification of relevant health informatics standards and the role of international standardization in support of eHealth were also important drivers.

This part of ISO/TR 14639 builds on lessons from many countries, including those whose activities are summarized in ISO/TR 14639-1 and was, in large part, inspired by experience with the Health Metrics Network (WHO/HMN Framework) activities sponsored by the World Health Organization (WHO). The particular focus of this part of ISO/TR 14639 is the potential for ICT to assist in the collection, communication, storage, processing, and use of information to support the delivery, planning, and coordination of health services; however, it also recognizes the importance of initial measures that involve paper-based collection and the need for a migration path from manual to semi-automated to fully automated information management systems.

The enterprise-wide business reference architecture described in this part of ISO/TR 14639 represents a starting point for the enterprise viewpoint or business layer of a comprehensive enterprise architecture, which would include other layers or viewpoints, such as the information/data, computational/function, engineering, and technology perspectives. This model would serve, for example, to assist in identifying initiatives and exploring the attributes of the components that would form a national eHealth strategy.

A comprehensive enterprise architecture is typically set up and maintained using a structured process that involves the following:

- a) an organized approach to ensuring that investments in ICT technology and information systems meet overall priorities for effective operation and delivery of healthcare services and the information needed for their planning, development, and continuous improvement;
- b) identifying and describing the main attributes of the eHealth information services, components, activities, and policies needed to support the operational requirements for health services within a jurisdiction (or organization);
- c) development of structured requirements for more detailed planning and investment in health information systems and for the development and dissemination of health information policies.

Where relevant, this part of ISO/TR 14639 takes advantage of and makes reference to the principles, policies, and specifications set out in relevant International Standards and existing architectural frameworks commonly used in the health sector including: ISO 12967, Health Informatics Service Architecture (HISA),^{[1][2][3]} the vision and principles of the World Economic Forum (WEF) Global Health Data Charter^[4] as seen in [Annex A](#), and the Health Enterprise Architecture Framework (HEAF).^[5] A layered approach to structuring of information architectures and models is proposed in this part of ISO/TR 14639, based on similar approaches such as the General Component Model introduced in

[Annex B](#),^[6] the WHO Health Metrics Network Framework,^[7] TOGAF,^[8] and the Zachman framework.^[9] In particular, HISA and the HEAF have been developed specifically to assist in the process of defining eHealth architectures for use in health services. See [Annex C](#) for more information on HISA. A short list of selected health informatics International Standards upon which the architectural components are based is found in [Annex D](#). See [6.1.4](#) regarding governance and national ownership of eHealth standards adoption and implementation.

In May 2012, WHO and ITU published a National eHealth Strategy Toolkit^[93] that embodies most of the concepts relevant to an Enterprise Architecture, tailored to the creation of a National eHealth Strategy. This resulted in a process that is exhaustive yet streamlined and easier to understand and apply. The Toolkit presents a thorough step-by-step set of methods, checklists, and examples to be used by country or region-level managers when developing an eHealth Strategic Vision, an eHealth Action Plan, and a Monitoring and Evaluation Plan. The WHO-ITU National eHealth Strategy Toolkit and ISO/TR 14639-1 and this part of ISO/TR 14639 form a complementary set of tools for the design and deployment of an eHealth architecture.

The architectural components and their characteristics as described in this part of ISO/TR 14639 are designed to be reviewed and, where appropriate, adopted by countries and subordinate health authorities at a level relevant to their specific needs. In particular:

- a) The components and characteristics may be used as model requirements in developing enterprise architectures or as a means of assessing and improving eHealth maturity.
- b) Each component is configurable to meet local needs by describing characteristics indicative of a range of capability from the most basic through to the highly advanced.
- c) The characteristics of various capacity levels for each component form the basis of the underlying maturity model.
- d) Typical starting points for the development of capability are provided for each of the components at the lowest maturity level, together with the basic principles the architecture should adhere to.
- e) There is an emphasis on developing appropriately layered, well-structured eHealth architectures with well-defined and preferably standardized interfaces between the various components and layers.
- f) There is a particular focus on potential eHealth requirements relevant to low- and middle-income (LMIC) countries.

Health informatics — Capacity-based eHealth architecture roadmap —

Part 2: Architectural components and maturity model

1 Scope

This part of ISO/TR 14639 provides a guide to best practice business requirements and principles for countries and their subordinate health authorities planning and implementing the use of information and communications technology (ICT) to support the delivery and development of healthcare. A business reference architecture is described in terms of components and capabilities that health authorities may use as a framework for building their own eHealth architectures and also for measuring the maturity of their health systems' use of ICT to support the delivery and development of healthcare.

It is worth noting that while this part of ISO/TR 14639 was developed with a particular view to support low- and middle-income countries, it can also be a useful guide for any country. Even if maturity is high in some aspects, highly developed countries may still need advice on architectural components for some aspects of a total eHealth system.

The development of eHealth architectures based on the guidelines set out in this part of ISO/TR 14639 will facilitate and optimize investments in Health Information Systems to achieve the following goals:

- a) information being used cost-effectively for improvement of health services;
- b) health information being harmonized, consistent, accessible, and able to be used effectively;
- c) patients, health professionals, and policy-makers having the right data available to make decisions about health services, treatment, and delivery of care;
- d) appropriate information being available to support evidence-based practice and health services planning, health services quality, and safety and to improve public health;
- e) improving accessibility to healthcare services;
- f) supporting harmonization of Health Information Systems and health information standards.

It is envisaged that this part of ISO/TR 14639 will be a valuable source of information for

- g) personnel responsible for health services policy, planning, and provision,
- h) those developing health information resources and eHealth policy at national and subordinate levels in a country,
- i) non-governmental organizations (NGOs) and others seeking to support or implement systems for information gathering, statistics, and care delivery in developing and emerging economies,
- j) developers and implementers of Health Information Systems and services,
- k) academic and research institutions and students in health informatics, and
- l) other stakeholders in the health sector.

This part of ISO/TR 14639 also proposes a maturity model and methodology that organizations may consider in developing and evolving their eHealth capacities in specified areas of operational capability from low to medium to high levels. The proposed business reference architecture identifies components

and capabilities needed to support various health service activities along with the governance, infostructure, and ICT infrastructure that is necessary for the effective and efficient use of information in the delivery and development of health services.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1.1

architecture system

<general> structure of components, their functions, and their inter-relationships and the principles and guidelines governing their design and evolution over time

[SOURCE: Adapted from Open Group Architecture Framework (TOGAF), 2009.]

2.1.2

architecture system

<data> description of the structure and behaviour of a system, a system's components, its functions and inter-relationships

[SOURCE: Adapted from Blobel B., Application of the Component Paradigm for Analysis and Design of Advanced Health System Architectures, 2000.]

Note 1 to entry: See definition of *system architecture* ([2.74](#)).

2.2

business reference architecture

reference architecture that is evolved based on a set of identified, high-level business requirements (functional, non-functional, and relevant supporting processes) for an enterprise, which the overall enterprise strategy and its infrastructure (business and IT) must support

[SOURCE: Adapted from IBM Tivoli Reference Architectures and the SKMT definitions of business architecture from Canada Health Infoway.]

Note 1 to entry: This architecture also needs to take into consideration the “wants and needs” of the clients served that may not map exactly to business drivers but nonetheless offer functional value to clients. It is the business “blueprint” for how a technical project will roll out and what it is trying to accomplish.

Note 2 to entry: See definition of *reference architecture* ([2.65](#)).

2.3

care plan

personalized statement of planned healthcare activities relating to one or more specified health issues

[SOURCE: EN 13940-1:2007]

2.4

chronic disease

health condition of 3 months duration or longer

[SOURCE: U.S. Centers for Disease Control and Prevention (CDC) National Center for Health Statistics]

2.5

classification

terminology which aggregates data at a prescribed level of abstraction for a particular domain

[SOURCE: ISO/TS 17117:2002]

2.6

client

person receiving social or medical services

2.7

clinical data warehouse

CDW

grouping of data pertaining to a health system or sub-system, possibly of diverse sources, accessible by a single data management system that enables secondary data analysis for questions relevant to understanding the functioning of that health system or sub-system, and hence supporting proper maintenance and improvement of that system or sub-system

[SOURCE: Adapted from ISO/TR 22221:2006.]

Note 1 to entry: A CDW tends not to be used in real-time; however, depending on the rapidity of transfer of data to the data warehouse and data integrity, near real-time applications are not excluded.

2.8

clinical decision support

type of system that assists healthcare providers in making medical decisions

[SOURCE: Health Level Seven International (HL7)]

Note 1 to entry: These types of systems typically require input of patient-specific clinical variables and, as a result, provide patient-specific recommendations.

2.9

clinical information

information about a person, relevant to his or her health or healthcare

[SOURCE: ISO 13606-1:2008]

2.10

clinical process

set of interrelated or interacting healthcare activities performed by one or more healthcare professionals

[SOURCE: ISO 18308:2011]

2.11

clinical vocabulary

system of standardizing the terms used in describing client-centred health and health service-related concepts

[SOURCE: ISO/TS 22789:2010]

2.12

community-based services

blend of health and social services provided to an individual or family at his/her place of residence or at other non-institutional locations within the community for the purposes of promoting, maintaining, or restoring health, minimizing the effects of illness and disability, and supporting and facilitating self-help and self-care

[SOURCE: Adapted from WHO 2004 A Glossary of Terms for Community Healthcare and Services for Older Persons.]

Note 1 to entry: Services and programs can include visiting nurses, delivered meals, home care, palliative care, community mental health, health education, screening, immunizations, family planning, sexual health, etc.

2.13

country income

classification of all World Bank member countries and all other economies with populations of more than 30,000 (213 total)

[SOURCE: World Bank Country Classification]

Note 1 to entry: Economies are divided according to 2009 GNI per capita, calculated using the World Bank Atlas method. The groups are: low income, \$995 or less; lower middle income, \$996 to \$3,945; upper middle income, \$3,946 to \$12,195; and high income, \$12,196 or more.

2.14

data warehouse

grouping of data, possibly of diverse courses, pertaining to a system or sub-system, accessible by a single data management system that enables secondary data analysis for questions relevant to understanding the functioning of that system or sub-system, and hence supporting its proper maintenance and improvement

[SOURCE: Adapted from ISO/TR 22221:2006.]

Note 1 to entry: A data warehouse tends not to be used in real-time; however, depending on the rapidity of transfer of data to the data warehouse and data integrity, near real-time applications are not excluded.

2.15

eHealth

use of information and communication technologies (ICT) for health

[SOURCE: World Health Organization (WHO) eHealth]

Note 1 to entry: In its broadest sense, eHealth is about improving the flow of information, through electronic means, to support the delivery of health services and the management of health systems.^[93]

Note 2 to entry: Health and health-related fields include healthcare services, health surveillance, health literature, and health education, knowledge, and research.^[26]

2.16

eHealth architecture

architecture of a system of eHealth components and services

[SOURCE: ISO 18308:2011]

2.17.1

electronic health record

EHR

<general> information relevant to the wellness, health, and healthcare of an individual, in computer-processable form and represented according to a standardized information model

[SOURCE: ISO 18308:2011]

2.17.2

electronic health record

EHR

<data> longitudinal electronic record of an individual that contains or virtually interlines to data in multiple EMRs and EPRs, which is to be shared and/or interoperable across healthcare settings and is patient-centric

[SOURCE: Adapted from ISO 18308:2011.]

Note 1 to entry: EHRs often capture data from multiple point-of-service systems and enable authorized access by the various providers of care to pertinent patient data across multiple service delivery locations or organizations in order to ensure continuity of care for the patient.

2.18
electronic health record architecture
EHRA

formal description of a system of components and services for recording, retrieving, and handling information in electronic health records

[SOURCE: ISO 18308:2011]

2.19
electronic medical record
EMR

electronic record of an individual in a physician's office or clinic, which is typically in one setting and is provider-centric

[SOURCE: European 2011 eHealth Strategies Final Report, January 2011]

2.20
enterprise architecture
EA

rigorous description of the structure of an enterprise, which comprises enterprise components (business entities), the externally visible properties of those components, and the relationships (e.g. the behaviour) between them

[SOURCE: Blobel B. Architectural; Methods Inf Med 2010 — modified]

Note 1 to entry: An enterprise architecture describes the terminology, the composition of enterprise components, and their relationships with the external environment and the guiding principles for the requirements (analysis), design, and evolution of an enterprise. This description is comprehensive, including enterprise goals, business processes, roles, organizational structures, organizational behaviours, business information, software applications, and computer systems.

2.21
health

state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity

[SOURCE: World Health Organization (WHO)]

2.22
health condition

aspect of a person or group's health that requires some form of intervention

Note 1 to entry: These interventions could be anticipatory or prospective, such as enhancing wellness, wellness promotion, or illness prevention (e.g. immunization).

[SOURCE: ISO/TR 12773-2:2009]

2.23
health information

information about a person relevant to his or her health

[SOURCE: ISO 18308:2011, 3.28]

2.24
health information system
HIS

system that combines vital and health statistical data from multiple sources to derive information and make decisions about health needs, health resources, health costs, uses of health services, and outcomes of healthcare

[SOURCE: Adapted from Canada Health Infoway, pan- Canadian Standards Electronic Drug Messaging (CeRx) Standards 1 –2010/03/29.]

2.25

health infostructure

foundational and up-to-date information and communications technologies (ICTs) developed, adopted, and implemented in the healthcare system to allow people (the general public, patients, and caregivers, as well as healthcare providers, health managers, health policymakers, and health researchers) to communicate with each other and assist them to make informed decisions about their own health, the health of others, and the health system

[SOURCE: Adapted from Canada's Health Infostructure, Health Canada.]

2.26

health issue

issue related to the health of a subject of care, as identified or stated by a specific healthcare party

[SOURCE: EN 13940-1:2007]

2.27

health record extract

attestable unit of communication of all or part of a health record

[SOURCE: ISO/TR 12773-2:2009]

2.28

health summary record

HSR

health record extract comprising a standardized collection of clinical and contextual information (retrospective, concurrent, prospective) that provides a snapshot in time of a subject of care's health information and healthcare

[SOURCE: ISO/TR 12773-2:2009]

2.29

health system

combination of components, activities, processes, and policies intended to promote, restore, and maintain health

[SOURCE: Adapted from WHO Health System Strengthening Glossary.]

2.30

health worker

person engaged in actions that are primarily intended to enhance health

[SOURCE: Adapted from World Health Report, January 01, 2006.]

Note 1 to entry: This term also includes healthcare worker.

2.31

healthcare

activities, services, or supplies related to the health of an individual

[SOURCE: EN 13940-1:2007]

2.32

healthcare activity

activity performed for a subject of care with the intention of directly or indirectly improving or maintaining the health of that subject of care

[SOURCE: EN 13940-1:2007]

2.33

healthcare professional

person authorized to be involved in the direct provision of certain healthcare provider activities in a jurisdiction according to a mechanism recognized in that jurisdiction

[SOURCE: Adapted from EN 13940-1:2007]

2.34

healthcare provider

healthcare professional or an organization involved in the direct provision of healthcare

[SOURCE: EN 13940-1:2007]

2.35

high-income country

HIC

country with a gross national income per capita of USD 12 746 or more

[SOURCE: World Bank Country Classification]

Note 1 to entry: A HIC is part of the classification system of all World Bank member countries (187) and all other economies with populations of more than 30,000 (213 total). Economies are divided according to 2009 GNI per capita, calculated using the World Bank Atlas method. The groups are: low income, \$995 or less; lower middle income, \$996 to \$3,945; upper middle income, \$3,946 to \$12,195; and high income, \$12,196 or more.

2.46

HL7 clinical document architecture

CDA

documentation that defines structure and semantics of medical documents for the purpose of exchange

[SOURCE: ISO/TR 18307:2001]

Note 1 to entry: CDA documents are encoded in extensible mark-up language (XML). They derive their meaning from the HL7 Reference Information Model (RIM) and use the HL7 Version 3 Data Types, which are part of the HL7 RIM.

2.47

HL7 v2.x (version 2.x)

series of electronic messages to support administrative, logistical, financial, as well as clinical processes, and primarily uses a textual, non-XML encoding syntax based on delimiters^{[18][190]}

[SOURCE: Health Level Seven International]

2.48

hospital information system

system that is used by end-users at the point-of-care or service, in this instance, a hospital

[SOURCE: Adapted from Canadian definition of point-of-care or point-of-service system in the SKMT Glossary Tool.]

2.49

integrated data repository

IDR

component of a health infostructure that maintains and manages the integrated common information generated in real-time by consolidating data from a variety of clinical sources to present a unified view (together with the related and required classifications, terminologies, ontologies, etc.), regarding the core business of the healthcare enterprise

Note 1 to entry: An IDR is also a key component of enterprise architecture modelling. Enterprise architecture is foundational for developing a health infostructure.

Note 2 to entry: The IDR can also be used for secondary purposes such as surveys, clinical research, statistics, reporting, and analysis.

Note 3 to entry: See definitions of health infostructure and enterprise architecture from References [36] and [30].

2.50
integrated disease surveillance (Africa Region)

IDSR

strategy by WHO African Region that includes communicable and non-communicable health conditions and events

[SOURCE: Integrated Disease Surveillance — WHO Regional Office for Africa]

2.51
interoperability

ability of two or more systems or components to exchange information and to use the information that has been exchanged

Note 1 to entry: See semantic *interoperability* (2.70) and syntactic *interoperability* (2.73).

[SOURCE: ISO/TS 27790:2009, 3.39, modified to add note to entry]

2.52
low-income country

LIC

low-income country as defined by the World Bank where income is USD 1,005 gross national income (GNI) per capita or less, calculated using the World Bank Atlas method

[SOURCE: Adapted from World Bank Country Classifications.]

Note 1 to entry: An LIC is part of the classification system of all World Bank member countries and all other economies with populations of more than 30,000 (213 total). Economies are divided according to 2009 GNI per capita, calculated using the World Bank Atlas method. The groups are: low income, \$995 or less; lower middle income, \$996 to \$3,945; upper middle income, \$3,946 to \$12,195; and high income, \$12,196 or more.

2.53
maturity model

set of structured levels that describe how well the behaviours, practices, and processes of an organization can reliably and sustainably produce required outcomes

2.54
middle-income country

MIC

middle-income country as defined by the World Bank country where income is between USD 1,005 and 12,275 gross national income (GNI) per capita or less, calculated using the World Bank Atlas method

[SOURCE: Adapted from World Bank Country Classifications]

Note 1 to entry: An MIC is part of the classification system of all World Bank member countries (187) and all other economies with populations of more than 30,000 (213 total). Economies are divided according to 2009 GNI per capita, calculated using the World Bank Atlas method. The groups are: low income, \$995 or less; lower middle income, \$996 to \$3,945; upper middle income, \$3,946 to \$12,195; and high income, \$12,196 or more.

Note 2 to entry: The MIC group is also split into Lower-Middle and Upper-Middle, below and above US \$3,975 respectively.

2.55
monitoring and evaluation

M & E

routine tracking of the key elements of program/project performance, usually inputs and outputs, through record-keeping, regular reporting and surveillance systems, as well as health facility observation and client surveys, and the episodic assessment of the change in targeted results that can be attributed to the program or project/project intervention

[SOURCE: Global Fund for AIDS, Tuberculosis, and Malaria (GFATM) Monitoring and Evaluation]

2.56

notifiable disease

any disease that is required by law to be reported to government authorities^[40]

Note 1 to entry: The 2005 WHO International Health Regulations (IHR) provides a list of events that involves cases of specific reportable diseases and reporting mechanisms.

2.57

organization

unique framework of authority within which a person or persons act or are designated to act towards some purpose

[SOURCE: Adapted from ISO/IEC 6523-1:1998, 3.1.]

2.58

patient

individual who is a subject of care

[SOURCE: Adapted from ISO/TR 20514:2005, 2.30]

2.59

personal health information

information that concerns a person's health, health history, health treatment, or genetic characteristics in a form that enables the person to be identified

[SOURCE: Adapted from ISO/TR 18307:2001.]

2.60

personal health record

PHR

representation of information regarding or relevant to the health, including wellness, development, and welfare of a subject of care, which may be stand-alone or integrating health information from multiple sources, and for which the individual, or their authorized representative, manages and controls the PHR content and grants permissions for access by and/or sharing with other parties

[SOURCE: ISO/IEC 2382-8:1998]

2.61

policy

rule or set of rules that speak to one or more legal, political, organizational, functional, business, technical, or related matters that may be expressed as obligations, permissions, or prohibitions

[SOURCE: Adapted from ISO/TS 22600-1:2006, 2.13.]

2.62

primary care

first level of care (access to first contact), characterized mainly by longitudinality, comprehensiveness, and coordination of care for the client within the overall health system

[SOURCE: Adapted from Starfield, B., Primary care: concept, evaluation and policy. New York, Oxford University Press, 1992]

Note 1 to entry: May have additional features such as family counselling and community and cultural competence

2.63

privacy

freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual

[SOURCE: ISO/IEC 2382-8:1998, 08.01.23]

2.64.1

Public health surveillance

<disease> systematic collection, analysis, interpretation, and follow-up of communicable or infectious diseases^[24]

[SOURCE: SKMT Glossary Tool]

2.64.2

Public health surveillance

<data> systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice^[96]

[SOURCE: WHO Health Topics — Public Health Surveillance]

Note 1 to entry: These activities are usually reactive in nature and can be used to track and monitor emerging outbreaks of illness that may influence public health wellness.

2.65

reference architecture

in the field of software architecture or enterprise architecture, provides a proven template solution for an architecture for a particular domain, as well as a common vocabulary with which to discuss implementations, often with the aim of stressing commonality^[13]

2.66

register

formal or official recording of items, names, or actions

[SOURCE: ISO/IEC 10036:1996, 3.3]

Note 1 to entry: This data should be maintained electronically so that it is accessible by other systems.

2.67

registry

directory-like system that focuses solely on managing data pertaining to one conceptual entity^[97]

[SOURCE: Canada Health Infoway Registry Messaging Standards]

Note 1 to entry: In an interoperable Electronic Health Record (iEHR), the registries store, maintain, and provide access to peripheral information not categorized as clinical in nature, but required to operationalize the EHR.

Note 2 to entry: The primary purpose of a Registry is to respond to searches using one or more pre-defined parameters in order to find and retrieve a unique occurrence of an entity.

Note 3 to entry: Examples of registries include Client Registry, Provider Registry, Location Registry, and Consent Registry.

2.68

roadmap

detailed plan to guide progress towards a goal

2.69

secure messaging

electronic communication between two parties that ensures only those parties can access the communication.^[99]

[SOURCE: Centers for Medicare and Medicaid Services, USA]

Note 1 to entry: The electronic message could be email or the electronic messaging function of a PHR, an online patient portal, or any other electronic means.

2.70

semantic interoperability

ability for data shared by systems to be understood at the level of fully defined domain concepts

[SOURCE: ISO 18308:2011, 3.45]

2.71

standard

document, established by consensus and approved by a recognised body that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at achievement of the optimum degree of order in a given context

[SOURCE: ISO/IEC Guide 2:2004]

2.72

subject of care

person seeking to receive, receiving, or having received healthcare

[SOURCE: EN 13940-1:2007]

2.73

syntactic interoperability

capability of two or more systems to communicate and exchange data through specified data formats and communication protocols

[SOURCE: ISO 18308:2011, 3.48]

2.74

system(s) architecture

conceptual model that defines the structure, behaviour, and views of a system

2.75

telehealth

use of telecommunication techniques for the purpose of providing telemedicine, medical education, and health education over distance

[SOURCE: ISO/TS 16058:2004, 3.13]

2.76

vertical program

program narrow in scope as opposed to one integrated across multiple domains, e.g. single versus multiple diseases^[24]

[SOURCE: SKMT Glossary Tool]

2.77.1

vocabulary

<domain> system of standardizing the terms used in describing a domain and the concepts related to that domain

[SOURCE: Adapted from ISO/TS 22789:2010; definition of clinical vocabulary.]

2.77.2

vocabulary

<terminology> terminological dictionary which contains designations and definitions from one or more specific subject fields

[SOURCE: ISO 1087-1:2000, 3.7.2]

3 Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
CDA	Clinical Document Architecture
eHAM	eHealth architecture model
EHR	Electronic Health Record
EMR	Electronic Medical Record
HIC	Health Information Custodian
HIS	Health Information System; Hospital Information System (context specific)
HIV	Human Immunodeficiency Virus
HL7	Health Level Seven
HMN	Health Metrics Network (WHO/HMN Framework)
HSS	Health System Strengthening
ICD	International Statistical Classification of Diseases and Related Health Problems
ICT	Information and Communications Technology
IDR	Integrated Data Repository
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organization
IMR	Indicator and Measurement Registry
ISO	International Organization for Standardization
ISO/TC 215	ISO Technical Committee 215 (Health Informatics)
IT	Information Technology
LIC	Low Income Country
LIS	Laboratory Information System
M & E	Monitoring and Evaluation
MIC	Middle Income Country
MoH	Ministry of Health
NGO	Non-governmental organization
PACS	Picture Archival Communications System
PHR	Personal Health Record
RIS	Radiology Information System
SDMX-HD	Statistical Data and Metadata Exchange — Health Domain

SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
TB	Tuberculosis

4 Overview of business requirements

This part of ISO/TR 14639 describes the components of an eHealth architecture supporting a comprehensive Health Information System (HIS). Not all components will be present in a country depending on strategic priorities and level of development.

The eHealth architecture model described in this part of ISO/TR 14639 is the result of discussions between the ISO/TC 215 expert group, invited experts, and country representatives. Broad-based input was sought from high-, medium-, and low-income countries and public health experts.

By mapping existing capacity to the architectural and maturity models, countries can identify capacity gaps in their strategic priorities. Levels of maturity (or capacity) have been defined for each of the eHealth architecture components to facilitate this analysis.

5 Development and application of eHealth enterprise architectures

5.1 eHealth enterprise architectures

eHealth enterprise architectures provide an organized approach to ensuring that investments in ICT technology and information systems meet overall priorities for effective operation and delivery of healthcare services and the information needed for their planning, development, and continuous improvement.

In general, enterprise architecture is a modelling tool that supports and facilitates the understanding, analysis, and design of enterprises. Enterprise architecture focuses mainly on the use of information technology, but tends to include all aspects of an enterprise, providing various perspectives, e.g. the strategic, business, and technology dimensions. An eHealth enterprise architecture thus identifies and describes the main attributes of the eHealth information services, processes, components, activities, and policies needed to support the operational requirements for health services within a jurisdiction (or an organization). This part of ISO/TR 14639 particularly focuses on the potential eHealth requirements of governments in emerging and developing countries or other authorities having responsibility for healthcare within an emerging or developing economy.

Having been developed, the eHealth architecture provides structured requirements for more detailed planning and investment in health information systems and for the development and dissemination of health information policies relevant to the needs of an emerging and developing economy.

5.2 Development of an eHealth architecture

5.2.1 Introduction

While the various requirements set out in this part of ISO/TR 14639 may be used to support any eHealth planning or acquisition activity, the principal objective is to help emerging and developing countries in the development and maintenance of local eHealth enterprise architectures by specifying common areas of likely requirements. These requirement specifications will also facilitate the development, acquisition, deployment, and implementation of compatible information systems.

- a) The development of an eHealth enterprise architecture involves the use of a structured process [often referred to as an enterprise architecture framework; refer to The Open Group Architecture Framework (TOGAF), Zachman, etc.]. An example is the Health Enterprise Architecture Framework (HEAF),^[5] which is being developed specifically to assist in the process of describing health services. Other existing standardization endeavours in healthcare and service architectures, for example,

ISO 12967 Health Informatics Service Architecture (HISA), represent best-practice elements for the adoption and establishment of enterprise architecture within healthcare.

- b) The components and requirements set out in this part of ISO/TR 14639 are designed to be reviewed and, where appropriate, adopted into a country's eHealth architecture according to each country's specific needs.
- c) The components and requirements are structured according to different levels of maturity models.
- d) The components and requirements provided in this part of ISO/TR 14639 are typical, optional, and configurable to meet local needs when being used in any specific eHealth architecture.
- e) The components recognize the importance of layering of an overall eHealth solution with well-defined and preferably standardized interfaces between the layers.

5.2.2 eHealth architecture model (eHAM)

Low-income countries (LICs) have little access to international standards development organizations (SDOs) for health informatics standards, or the standards they create due to barriers including awareness of standards, cost, and language. While efforts are under way to address these barriers, issues remain with education, interpretation, and proper adoption of standards, as well as establishment and verification of conformance criteria, preferably at the national level.

In the case of ISO/TC 215, for example, countries become national member bodies (NMB) with corresponding ISO mirror committees, standards infrastructure, and operating and membership costs including travel, which are unaffordable in LICs. WHO, as a result of this situation, has become increasingly involved in international standards development activities to help represent LIC interests.

A disproportionate number of high-income countries (HICs) in these SDOs may have introduced a bias towards HIC needs. A shift from programmatic and monitoring strategies in public health to more advanced electronic health record (EHR) systems and mobile technologies may reflect a HIC bias as much as a paradigm shift. Monitoring and Evaluation (M & E) analyses can help to establish the impact of different approaches and help guide strategy. While health system strengthening (HSS) requires multiple fronts, confusion about priority-setting can occur when competing needs are not evaluated against a framework and appropriate indicators.

Maturity models, which have been described in various domains, are a useful way to match capability with appropriate technology. This part of ISO/TR 14639 attempts to draw on this experience to define a model which can be used to guide standards adoption and related strategies in an appropriate, cost-effective, and timely manner.

This part of ISO/TR 14639 proposes that LIC capability be assessed against the eHealth architecture model (eHAM), a model introduced in ISO/TR 14639-1 that ISO/TC 215 has developed with input from WHO. The eHAM identifies the key components of an eHealth architecture. This model is used in [Clauses 6](#) and [7](#) as the reference for the maturity models articulated therein. For more detailed information on HISA, see [Annex C](#). The Introduction notes the three key elements of a structured process for setting up and maintaining a comprehensive enterprise architecture.

NOTE In ISO/TR 14639-1, the eHAM (eHealth architecture model) was referred to as the eHAMM (eHealth architecture maturity model). It has been renamed in this part of ISO/TR 14639 to more clearly reflect the fact that the architecture model drives the maturity models.

5.3 Building up the architecture: A methodology

5.3.1 Introduction

The eHAM describes country capacity to provide direction in health system strengthening in terms of components and services that need to be built according to well-defined national strategies. The building up of the single components and services to reach higher levels of maturity must however be enabled by a standard methodology, suitable to be implemented by all enterprises (including LICs) requiring robust

interoperable health informatics systems in their national eHealth architecture. The methodology must also provide direction to ensure that the enterprise maintains ownership and control of its core information assets, while maintaining openness of its architecture.

The methodology presented in the remaining parts of [Clause 5](#) is based on the concept of the integrated data repository (IDR) of the enterprise, which is widely known and accepted in enterprise architecture modelling as a component having the scope of maintaining and managing the integrated common core of operational information. The information is generated in real-time by consolidating data from a variety of clinical sources to present a unified view (together with the related and required classifications, terminologies, ontologies, etc.), regarding the core business of the healthcare enterprise (see for example ISO 12967 HISA as discussed in [Annex C](#)). The IDR can also be important for secondary purposes, such as surveys, clinical research, statistics, reporting, and analysis or simply to maintain all historical validated data for the enterprise (v.s. the live and real-time production data required for daily activities that the primary IDR usually contains).

The IDR concept also stems from the WHO Health Metrics Network Framework for National Health Information Systems illustrated in [Figure 1](#), but in this case mainly refers to the secondary purposes just mentioned

NOTE [Figure 1](#) was reproduced from Reference [Z], Figure 14, with kind permission of the World Health Organization (WHO).

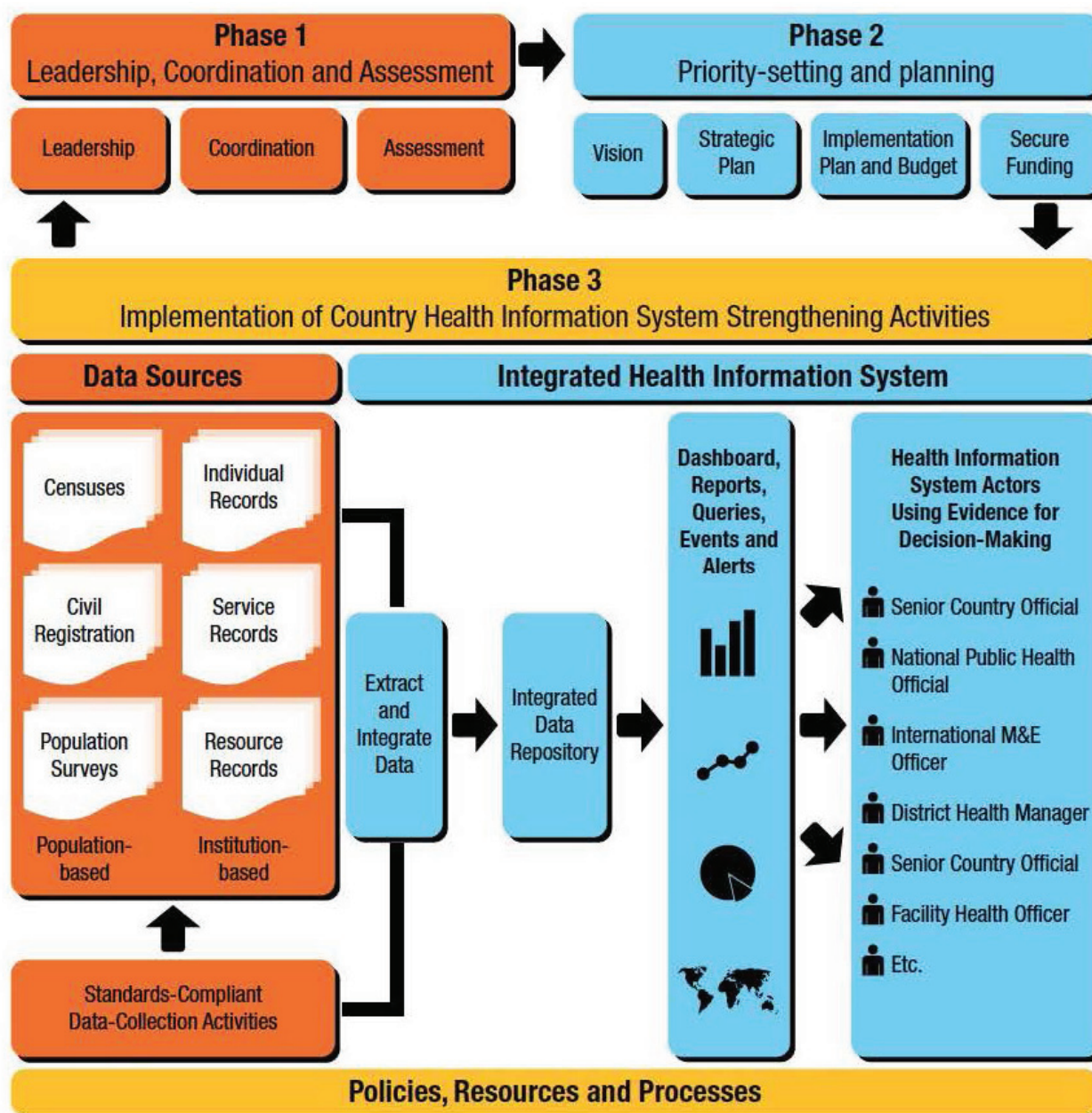


Figure 1 — Health metrics network framework

In the following, the ISO 12967 HISA standard, described briefly in [Annex C](#), shall be used to help in identifying

- the basic characteristics of the IDR component,
- the relationship between the IDR and the data-handling eHealth services, and
- how the approach including the IDR allows implementing a migration strategy towards a high-capacity eHealth architecture.

5.3.1.1 The Integrated Data Repository

The IDR plays a fundamental role in the eHealth enterprise architecture. It is widely recognized in literature that there is a need for a component that must (also) maintain and manage a common nucleus of information regarding the core business of the enterprise, making the existing information

assets available when and where needed through a standard service architecture, facilitating the interoperability of existing applications, and protecting investments in a strategy that supports future evolution. The ISO 12967 HISA standard supports such requirement and is used here to describe how to maintain a repository (or set of federated repositories) which maintains such common core data and makes it available to the enterprise through a service architecture. In other words, the IDR's scope is basically to support the architecture by integrating its common information assets. The general principles of HISA are to

- a) secure openness and vendor-independence,
- b) require that the common information asset be separated from specific applications or technology and be accessible through services,
- c) ensure that its information and service model is well-documented,
- d) ensure that the data it manages is under the sole property of the healthcare enterprise.

These principles, among others, ensure the enterprise is able to access its own information asset and allows optimization of its investments, since data is always made available when and where needed for carrying out of daily healthcare-related, organizational or statistical activities, guaranteeing interoperability, and avoiding redundant replication of data across systems. Since the common information asset is consistent and accessible by all users, daily routine activities will also automatically make it possible to meet other fundamental requirements of the healthcare enterprise, requirements that are frequently underestimated or treated in isolation, for example:

- a) the automatic creation of a life-time healthcare record;
- b) the combination of costs, activities, and clinical aspects to support research, statistical, and managerial needs;
- c) maintaining a high level of data quality, including data validation.

Such objectives are reached naturally by the component and service-based paradigm without the need for any duplication of systems or of workload by the users, as shown in [Figure 2](#).

NOTE [Figure 2](#) was reproduced from published materials pertaining to References [1], [2], and [3], with kind permission of GESI Gestione Sistemi per l'Informatica, Rome, Italy.

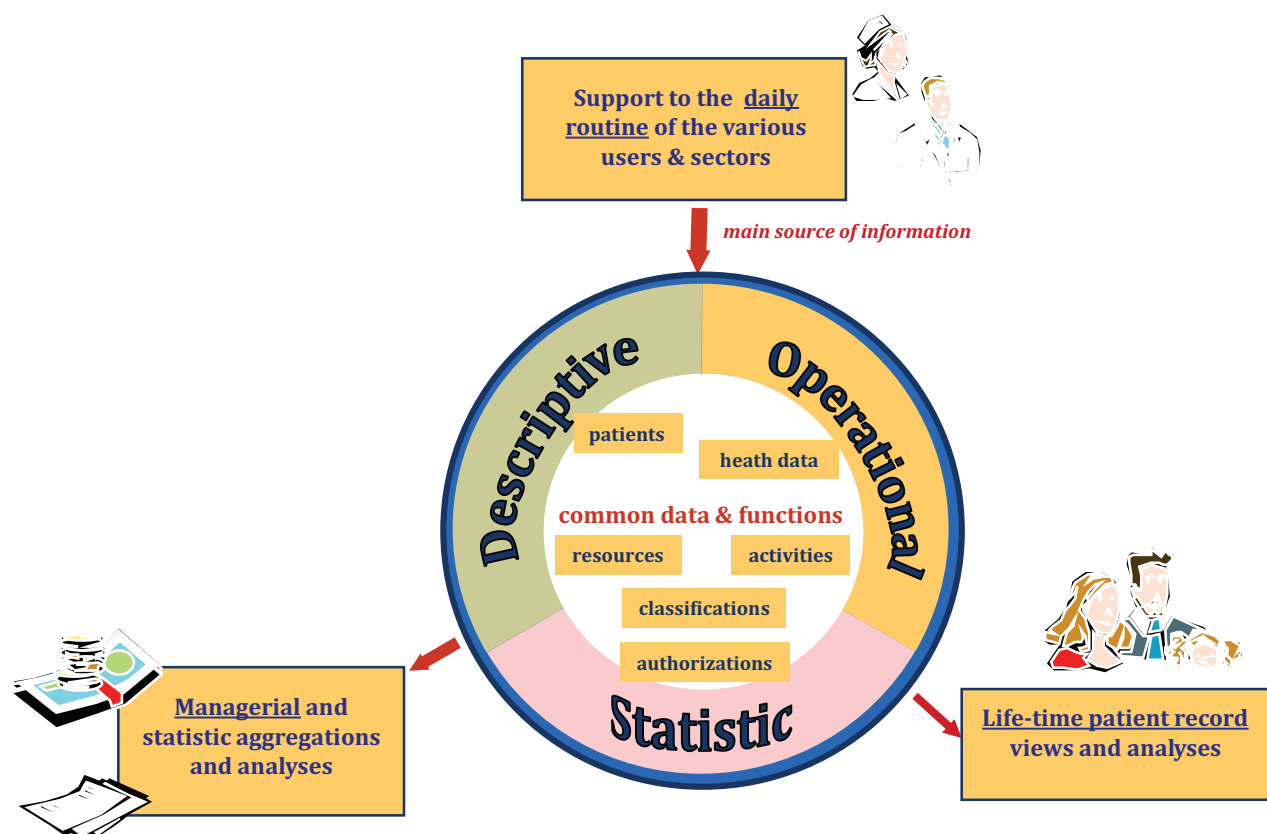


Figure 2 — Real-time gathering of information

5.3.1.2 eHealth services

As discussed in the previous point, the principle of a component acting as an IDR secures the HISA data-ownership principle by managing the enterprise's integrated information asset. eHealth information services, as described by the architecture, can be built in a technology-independent manner on top of the IDR, at least for the information considered common core of the enterprise, allowing the fruition of such information asset at different levels of the enterprise through a well-defined and documented interface. HISA provides a normative reference for documenting the interfaces of the services together with their expected behaviour (see [Annex C](#)).

These services shall be made available to diverse, multi-vendor applications through many types of implementations, allowing each part of the enterprise to use the technological infrastructure best suited to its needs. All aspects (i.e. clinical, organizational, and managerial) of the healthcare structure must be supported by the architecture, which must be able therefore to comprise all relevant information and all business workflows, structuring them according to criteria and paradigms independent from specific sub-domain aspects, temporary requirements, or vendor specific technological solutions.

5.3.2 Evolution towards a high-capacity eHealth architecture

The different eHealth capacity levels, described in [Clause 6](#), are cumulative and intended to illustrate a typical path towards more sophisticated eHealth systems over time and to assist with structuring discussions of actual eHealth enterprise architecture. Each level includes health process domain components, foundation (eHealth infostructure components) and foundation (ICT infrastructure components). Governance and national ownership act as the overarching, oversight framework for the model.

The planning and evolving of the eHealth architecture steps from low to medium up to high capacity can be carried out by following an incremental methodology, as proposed by ISO 12967 HISA: incrementally building up the required eHealth services using the IDR as methodological infrastructure, each step in the

individually capable both of embedding an internal logic and of encapsulating the information elements. The common core information asset is read on one side in each service but incrementally extended with further real-time data generated by the use of the services. In this vision, the IDR's information model (organizational, clinical, and managerial), together with its service architecture become the information and computational reference models for the healthcare enterprise.

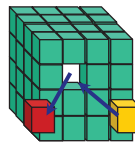
Different products, systems, and services can coexist, while at the same time distributed environments can be gradually implemented and evolved, and even existing legacy modules or components of the information system, once encapsulated with proper services, can become part of the accessible architecture. Initially, only the basic set of services identified by the healthcare enterprise need to be implemented to satisfy the initial low capacity architecture requirements of LICs.

As the system and the needs grow, the reference models and the IDR shall be extended to cover further information objects and on top of these new functionality (services) can be developed without the need of designing and implementing ad hoc (and fragmented) legacy systems and databases, but directly using the service architecture for accessing and manipulating the totality of the relevant and integrated data, which includes information directly generated by the services and information created by other applications of the system encapsulated in the service architecture. At the end, the system will slowly evolve towards the high capacity architecture as planned by the growing economy itself. Without any ambition to describe the architectural models behind the methodology (described in the Annexes), [Figure 3](#) illustrates the benefits of using a sound architectural approach and methodology based on standards.

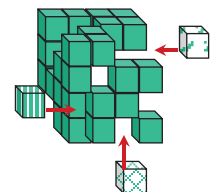
NOTE [Figure 3](#) was reproduced from published materials pertaining to References [1], [2], and [3], with kind permission of GESI Gestione Sistemi per l'Informatica, Rome, Italy.

The HISA methodological approach for building up an incremental Service Architecture based on the IDR facilitates:

Vendor independence, allowing substitution of components without imposing changes to the others

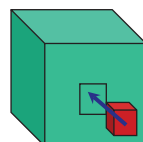


Incremental construction of open architectures, adding modules using/providing common services



Evolution of existing (monolithic) systems

Substitution of old parts



Introduction of re-usable extensions

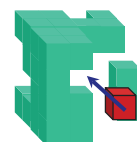


Figure 3 — Benefits of HISA approach

5.3.3 Planning the evolution

This evolutionary approach allows all players in the national eHealth program to collaborate. Suppliers are able to plan and design components of the architecture, capable of interoperating. LICs can plan the implementation and evolution of the system at the strategic level and validate the compliance of different solutions with respect to standards and the needs of the enterprise, thereby facilitating the selection of different but interoperable products.

In general, such a foundation provides the roadmap for evolutionary steps, detailing the various elements of the service architecture up to a level permitting the physical connection of different products in an open environment.

6 Health architecture components and requirements

The following model introduced in ISO/TR 14639-1 identifies the key components of an eHealth architecture used as the basis of the maturity model described throughout this part of ISO/TR 14639.

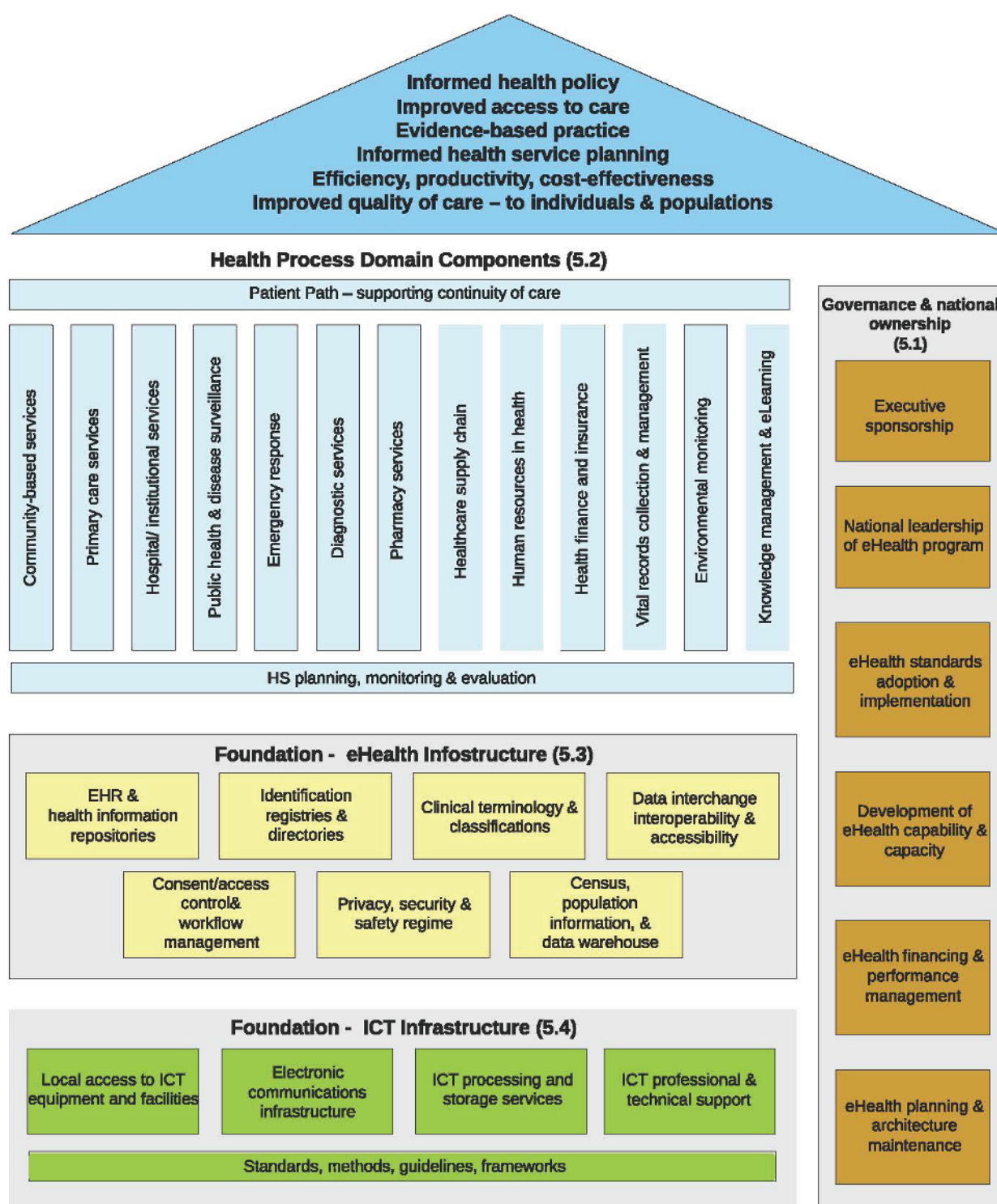


Figure 4 — eHealth architecture model

[Source: Adapted from ISO/TR 14639-1.]

This eHealth architecture model comprises different components that are aggregated under the following general categories.

- Foundation components — ICT infrastructure:** This is shown as the bottom layer of [Figure 4](#), represented in green, and encompasses the core IT technologies including networking, servers,

software, and IT human resources. In general, this is the most commonly found category in any country, all underpinned by relevant standards, methods, guidelines, and frameworks. [6.4](#) discusses each of the elements of the ICT infrastructure and the related Maturity models.

- b) **Foundation components — Infostructure:** This is shown as the middle layer of [Figure 4](#), represented in yellow. It includes EHR repositories, registries, data interchange interoperability, consent and access control, privacy, and security and data warehousing. Standards are also a key component of the eHealth infostructure although not explicitly called out in the eHealth architecture model (eHAM) diagram. It should be assumed that the adoption and use of standards is integral to each and every component of the infostructure shown. The proper utilization of standards will define how robust and scalable the final application of the eHealth platform will be. [6.3](#) details each of the elements in this category and the related maturity models.
- c) **Health process domain components:** This is shown as the upper layer of [Figure 4](#), represented in aqua. This category contains the different health domains that should be present in a national eHealth strategy. Note that human resource information and healthcare supply chain systems are also part of this component of the model. Although not specific to health, it is common that in many low- and middle-income countries (LMIC), these components are not present and have to be developed to address the healthcare needs. The management and allocation of human resources are key issues for any country, especially for LMIC where higher trained and educated health personnel such as nurses and physicians are rare. [6.2](#) details each of the elements in this category and the related maturity models.
- d) **Governance and national ownership:** This is shown as the vertical bar on the far right of [Figure 4](#), represented in brown. This is an important category of the eHealth architecture model since it represents the organizational and governance aspects of eHealth, including the financing, performance management and the development of local capability and capacity in Health Informatics. [6.1](#) details each of the elements in this category and the overall corresponding standards, cross-references, and dependencies for [Clause 6](#).

Successful development, implementation, maintenance, and evolution of all of these components of the eHealth architecture will help a country to achieve the improvements and benefits shown in the pyramid (roof) at the top of the model (in sky blue), improved quality of and access to care, improved efficiency, productivity and cost-effectiveness, informed health policy, and increased evidence-based practice.

6.1 Governance and national ownership

6.1.1 Description

Governance of eHealth can be defined as the overarching framework that ensures that all of the components of the eHealth architecture work independently but in dynamic coordination. It encompasses aspects of leadership, strategy, investment, financing, legislation, policies, and regulation.

Governance of IT is a well-known body of knowledge and practice that provides the opportunity to understand and learn to develop the fundamental components required to facilitate the delivery of informatics to support quality care, a learning culture, and an ethos by which staff are valued and supported as they form partnerships with stakeholders, especially patients and non-IT healthcare workers. IT governance demands the re-examination of traditional roles and boundaries, between informatics and health professions, physicians and patients, and managers and clinicians, so that together, they can make the most of, and reap the most from IT with respect to improving the quality of their services while safeguarding information privacy and security.

National governance of eHealth embodies IT governance, but goes beyond that since the articulation among components, processes, and stakeholders is more diverse and complex in the healthcare domain when compared to other domains. To illustrate this, the typical length of time for national eHealth strategies to start showing results is around seven years^{[76][77]} which in itself stresses the need for the eHealth strategy to be able to survive changes in government, not an easy requirement in general and especially in LMICs.

Governance is required for developing a national eHealth vision and managing its implementation. The national eHealth vision is an extension of, and intrinsically entangled with the existing national health system. Mature health systems have clearer requirements and demands for eHealth.

Governance of eHealth aims to keep the eHealth architecture efficient and flexible enough to support the ever-changing needs of the healthcare system, yet consistent and robust enough to ensure information safety and quality.

eHealth governance can be viewed as the guardian of the eHealth strategy, ensuring that local needs can be treated locally and independently while the eHealth architecture and the formed set of laws, regulations, and technological standards ensures interoperability in the widest possible sense (syntactic, semantic, purposeful, legal, ethical) and adherent to and aligned with the overall health system needs.

The objective of governance is to determine and cause the desired behaviour and results to achieve the strategic impact of IT. It defines a system in which the managers monitor, evaluate, and direct IT management to ensure effectiveness, accountability, and compliance of IT solutions.

Governance involves the active distribution of decision-making rights and accountabilities among different stakeholders in an organization and the rules and procedures for making and monitoring those decisions to determine and achieve desired behaviours and results. It includes defining the following:

- a) Who makes directing, controlling, and executing decisions?
- b) How the decisions will be made?
- c) What information is required to make the decisions?
- d) What decision-making mechanisms will be required?
- e) How exceptions will be handled?
- f) How the governance results should be reviewed and improved?

Some benefits of IT Governance are the following:

- a) achieving business objectives by ensuring that each element of the mission and strategy are assigned and managed with a clearly understood and transparent decisions, rights, and accountability framework;
- b) defining and encouraging desirable behaviour in the use of IT and in the execution of IT outsourcing arrangements;
- c) implementing and integrating the desired business processes into the organization;
- d) providing stability and overcoming the limitations of organizational structure;
- e) improving customer, business and internal relationships and satisfaction, and reducing internal territorial strife by formally integrating the customers, business units, and external IT providers into a holistic IT governance framework;
- f) enabling effective and strategically aligned decision-making for the IT Principles that define the role of IT, IT Architecture, IT Infrastructure, Application Portfolio and Frameworks, Service Portfolio, Information and Competency Portfolios, and IT Investment and Prioritization.

In mature health systems, eHealth practice is supported by thorough policies and legislation regarding the collection, storage, processing, access to and use of identified data. A combination of policies, legislation, and regulation is also required to ensure good practice, patient rights, and privacy when systems exchange clinical data, moreover across state, provincial, and even country borders.

National ownership is thus a requirement for both designing and supporting the eHealth architecture.

6.1.1.1 Examples of applicable standards, cross-references, and dependencies

Although there are few standards that help in designing governance of eHealth, there are several IT governance standards that support and complement the views expressed in this Clause and the subsequent Clauses.

The standards identified here are Australian Standards (AS) and cover areas related to the establishment of leadership and processes associated with the implementation and management of IT architecture. While not related per se to architecture, they are required for its sustainability.

The following set of standards provides a framework of principles for top managers to use when evaluating, directing, and monitoring the use of information technology (IT) in the health enterprise:

- a) Good Governance Principles (AS8000);[\[146\]](#)
- b) Fraud and Corruption Control (AS8001);[\[147\]](#)
- c) Organizational Codes of Conduct (AS8002);[\[148\]](#)
- d) Corporate Social Responsibility (AS8003);[\[149\]](#)
- e) Whistle Blower protection programs (AS8004);[\[150\]](#)
- f) Good Corporate Governance (GCG) for ICT (AS8015).[\[151\]](#)

The widely acknowledged AS4360 risk management standard was also revised in 2004. This, along with the adoption of BSI5000 (now ISO/IEC 20000) as AS8019 IT Service Management, provided the context for the drafting and subsequent publishing of AS8015 Good Corporate Governance for ICT to provide guidance on the small “c”, corporate governance of Information and Communication Technology.

ISO/IEC 38500:2008 provides guiding principles for directors of organizations (including owners, board members, directors, partners, senior executives, or similar) on the effective, efficient, and acceptable use of information technology (IT) within their organizations and on the governance of management processes (and decisions) related to the information and communication services used by an organization. In addition to the six principles for good corporate governance of IT set out by ISO 38500, the principle of integrity and ethics as defined by ISO 19011:2011 is integrated as preferred behaviour to guide decision-making:

- a) Principle 1: Establish clearly understood responsibilities for IT;
- b) Principle 2: Plan IT to best support the organization;
- c) Principle 3: Acquire IT validly;
- d) Principle 4: Ensure that IT performs well, whenever required;
- e) Principle 5: Ensure IT conforms with formal rules;
- f) Principle 6: Ensure IT use respects human factors;
- g) Principle 7: Integrity and Ethics (new principle using ISO 19011:2011 and ISO/IEC 27007 which largely refers to ISO 19011, draws on ISO 17021, and aligns with ISO/IEC 27006.:
 - 1) Personal IT behaviour: ethical i.e. fair, truthful, sincere, honest and discreet;
 - 2) Integrity: the foundation of professionalism; auditors and the person managing an audit IT program should
 - i) perform their work with honesty, diligence, and responsibility,
 - ii) observe and comply with any applicable legal requirements,
 - iii) demonstrate their competence while performing their work,

- iv) perform their work in an impartial manner, i.e. remain fair and unbiased in all their dealings, and
- v) be sensitive to any influences that may be exerted on their judgment while carrying out an audit.

6.1.2 Executive sponsorship

6.1.2.1 Description

In order to succeed, any eHealth strategy and the architecture it embodies needs to be resilient to time and impervious to questionable or unplanned changes in government agendas. As mentioned before, solid results from the use of organized national eHealth initiatives take years to show. This implies that the top government must hold ownership of the eHealth initiative and provide effective Executive Sponsorship. The Executive Sponsor's main goal is to promote top-down organizational commitment, which includes identifying key stakeholders, making them understand the complexity of the initiative, the expected deliverables, and the times required to deliver them.

One of the Executive Sponsor's most important objectives is to define the organizational locus that will govern the eHealth program or initiative. In countries with mature health systems, this is often a national leadership that is hosted in somewhat independent bodies, especially created for this purpose. Such bodies are more stable and likely to outlive changes in local, regional, federal, or national governments. Canada Health Infoway is one example of this model.^[28]

6.1.2.2 Maturity model

6.1.2.2.1 Low

- a) There is little or no national eHealth architecture or even eHealth strategy.
- b) Applications of eHealth are mostly stand-alone and defined by local needs.
- c) Governance at the national level is mostly inexistent.
- d) Leadership is poor and, where it exists, is exercised mostly at the local level.
- e) Legislation, policy, and regulation for eHealth are insufficient or non-existent.

6.1.2.2.2 Medium

- a) There is some eHealth planning that points to the need for an eHealth architecture.
- b) There are bodies that produce directions at the national level, but these are not properly aligned among themselves, nor are they aligned with the regional and local levels.
- c) There are pieces of legislation, regulation, and policy that apply to eHealth, but most of them originate from and are based on general IT needs rather than health system specific needs.

6.1.2.2.3 High

- a) There is a clearly defined and publicized eHealth strategy, of which the eHealth architecture is an essential part.
- b) There are formal instruments that describe an eHealth Program, with budget and the description of the bodies that will coordinate it.
- c) Executive Sponsorship is well-established, clearly understood and widely recognized throughout the country.

6.1.3 National leadership

6.1.3.1 Description

Strong national leadership is required to set an eHealth initiative in motion and keep it running steadily and efficiently, while ensuring adherence to national strategic goals.

The development and maintenance of the eHealth architecture implies a special effort for the country, as it requires dedicated resources that must be sought after, allocated, and managed according to the defined eHealth architecture.

Among other tasks, the national leadership activities include the following:

- a) orchestrating eHealth activities, so that stakeholders, including legislators, regulators, IT staff, regional and local health authorities, patient representatives, public and private investors are aware of the eHealth initiative, the results they are expected to get, the contributions they are expected to make, and the time frame within which these activities will be carried out;
- b) analysing stakeholders needs;
- c) championing the initiative, providing suitable exposure to, and actively seeking and obtaining buy-in from stakeholders;
- d) engaging with stakeholders and communicating the importance and value that the eHealth architecture will bring to the country, including making the business argument for the eHealth architecture initiative;
- e) showing the healthcare community that the executive level is backing this initiative with confidence;
- f) providing necessary funding and resources as appropriate, by governing the resources required to plan, design, create, implement and maintain the proposed eHealth architecture;
- g) providing direction to the teams responsible for eHealth architecture in the country;
- h) providing transparency.

In countries with mature health systems, the national leadership tends to be exerted by a formally assigned body which relies on Executive Sponsorship and answers to top-level stakeholders, such as regional and national governments.

6.1.3.2 Maturity model

6.1.3.2.1 Low

- a) There is little or no national leadership.
- b) There is little coordination among national eHealth initiatives.
- c) Stakeholders have little or no understanding of whether there is a plan or even a roadmap for eHealth initiatives.

6.1.3.2.2 Medium

- a) There is some national leadership recognized nationally but it is insufficient to engage with stakeholders to generate a coordinated movement.
- b) eHealth initiatives are somewhat coordinated but lack overall alignment towards objectives that exist but are not clearly stated.
- c) The leadership is able to induce the production of pieces of legislation, regulation, and policy specific to eHealth, but they tend to be fragmented and insufficient.

6.1.3.2.3 High

- a) There is a clearly defined body, formally and informally recognized as the national leadership for eHealth. Its constitution and objectives are supported by the eHealth strategy. It is widely recognized as knowledgeable, inspiring, and a good facilitator.
- b) The leadership has assembled people from a wide variety of backgrounds to create consensus on comprehensive and robust legislation, regulation and policies specific to eHealth.

6.1.3.3 Examples of applicable standards, cross-references, and dependencies

See [6.1.1.1](#).

6.1.4 eHealth standards adoption and Implementation

6.1.4.1 Description

The adoption and use of standards for eHealth is a complex task even in small settings. Standards are essential for data collection, representation, and storage as well as information exchange. There is no possible way for systems to interoperate without Health Informatics standards. However, choosing which standards to use, assembling them together in a meaningful platform, making them available to all stakeholders, enabling stakeholders to use them by building capacity, and providing reference models or implementations are major tasks that are best done by a combination of top-down and bottom-up approaches.

Complexity arises also from the fact that, usually, there are international, as well as national, “de facto” and “de jure” Standards Development Organizations (SDOs) providing standards that are either insufficient or redundant, sometimes both. In less mature or in very simple environments, it is possible for the central government to dictate most health informatics standards that are used throughout a country.^[76] However, in most countries, dealing with such aspects involves harmonization and, as part of achieving this, consensus-building. Therefore, the existence of consensus forums for standards adoption and implementation is an important component of governance of eHealth. Besides being aligned with the national leadership, the consensus forums must include wide representation, especially from SDOs and other standards-supporting organizations, within the country and, if the national standards capacity is poor, representation from abroad. Such standards consensus forums work together with the National Leadership to engage with non-SDOs to promote understanding of the use of standards.

In some countries with more mature health systems, standards forums work with recognized needs and evolve towards identifying and adopting the sets of standards that will meet those needs. This is a process that requires robust governance and clear ownership regarding choosing, translating, harmonizing, disseminating, maintaining, and supporting the standards. Note that in many cases, standards maintenance and evolution is kept outside the reach of the national leadership, which may require extra governance. Apart from that, for many countries, international standards are written in a foreign language (English). Translating a standard and keeping that translation up-to-date poses additional strain on standards governance.

Standards forums’ activities include the following:

- a) identifying the relevant standards that are needed for the country;
- b) providing the mechanisms that ensure such standards will be adopted. Most standards adoption processes will include the need for some translation, adaptation, harmonization, definition of capacity-building requirements, and creation of special organizational structures to take care of them, provision of infrastructure and personnel and the required funding necessary to support all of these undertakings;
- c) assuring stakeholders that, if standards are followed, they can have confidence in the use of eHealth systems;
- d) informing and guiding eHealth professionals in the use of health informatics standards.

6.1.4.2 Maturity model

6.1.4.2.1 Low

- a) Standards when in use are defined locally, many times on an application basis.
- b) There are no or few nationally defined guidelines or mandated requirements, even for basic standards for health informatics, apart, probably, from ICD.
- c) Stakeholders see little value in the use of standards and are more likely to disregard them, because of their costs and other difficulties involved in adoption, including real and perceived negative impacts on healthcare provider workflows, at least initially.

6.1.4.2.2 Medium

- a) There are some national guidelines on which standards to use, most of them for billing purposes.
- b) There are several national, regional, or sector specific SDOs, developing redundant or insufficient standards.
- c) Most stakeholders recognize that standards are important but fail to see they are worth the required investment.
- d) Knowledge and field experience in the use of standards is lacking. Standards are chosen ad hoc, as needs arise.

6.1.4.2.3 High

- a) Standards are widely recognized by stakeholders as an essential part of eHealth.
- b) There are formal and coordinated consensus forums to discuss and develop the whole standards lifecycle, from identification to implementation and maintenance.
- c) There are enough health informatics professionals to help conceive, develop, and use eHealth applications that interoperate among them.
- d) Standards are maintained and evolved by bodies specifically assigned to take care of them nationally, but there are formal structures that support the use and evolution of standards nationally, regionally, and locally.

6.1.4.3 Examples of applicable standards, cross-references, and dependencies

See [6.1.1.1](#).

6.1.5 Development of eHealth capability and capacity

6.1.5.1 Description

eHealth capability and capacity development is a critical element in a country's eHealth strategy because a sufficient number of skilled individuals who can plan, implement, and sustain eHealth investments is essential if a high maturity level is to be achieved. Health informatics (HI) is a unique set of skills because it is multi-disciplinary. Health informatics has been defined as "the intersection of clinical, information management (IM), information technology (IT), and management practices", as depicted in [Figure 5](#).
[199]

NOTE [Figure 5](#) was reproduced from Reference [199], with the kind permission of COACH, Canada's Health Informatics Association.

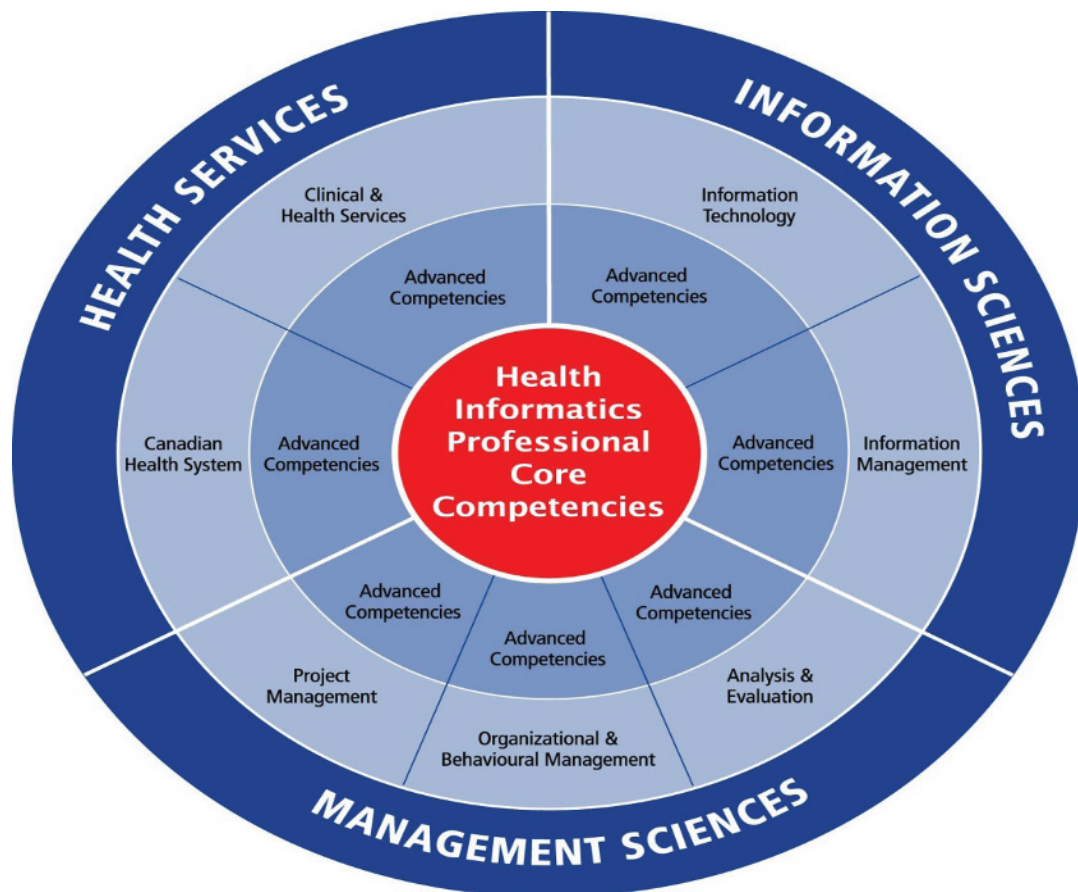


Figure 5 — Health informatics scope of practice

Currently, given the demand for and continuing growth in demand for eHealth resources, many individuals have arrived into the eHealth field from another profession e.g. information technology or healthcare provision, and often need to be trained in the complementary disciplines. HI itself is a relatively new discipline with a rapidly evolving body of knowledge. Achievement of the requisite education and skills (capabilities) is occurring through a variety of approaches, including on-the-job training, short courses, degree courses at higher education institutions (HEIs), post-graduate degrees focused on eHealth, and the inclusion of eHealth in the curricula for health professionals' education.

In developed countries, the capacity of health informatics training programs is beginning to grow and produce new graduates, new national professional associations for health informatics professionals are being established and/or existing associations have begun either registering or certifying health informatics professionals and implementing continuing education requirements.

In addition to building the relevant knowledge and skills (capability), there is a need to build a pool of HI resources (capacity). Even in developed countries, human resources with a broad-based skill set in HI are at a premium. People with this cross-section of skills are necessary because they can function more effectively as part of the interdisciplinary teams that are necessary to implement eHealth strategies.

Further, skilled individuals need to be employed in positions that enable them to use their HI capabilities and grow them further; motivated to achieve through a clear career path. In these positions, eHealth professionals will ensure skills transfer and mentor those who are less experienced.

Canada's Health Informatics Association (COACH), has created a set of core competencies that illustrate how health informatics spans across the three main source disciplines of health, information and management sciences. An example of the diversity of jobs needed to support a mature eHealth infrastructure is reflected in Canada's HI Career Matrix.^[79]

In summary, countries should consider some combination of the following strategies in developing the human capability and capacity needed to support eHealth programs:

- a) building a core of health informatics professionals within their eHealth workforce with a defined set of competencies pertinent to the country's current and forecasted eHealth needs which is then augmented by a professional certification program and continuing education requirements;
- b) a broadening array of health informatics training and education programs, ranging from bridging programs to supplement the skills of new entrants from other industries and professions and a set of HI education programs (diploma, baccalaureate, and masters level);
- c) targeted educational events focused on providing training on new technologies and best practices, which the country is adopting in its eHealth program;
- d) support for on-the-job training, short courses (remote, off-site, after hours), and the development of further degree courses through higher education, which teach not only core HI skills but also provide opportunities for specialization;
- e) programs that engage, motivate, and inspire individuals e.g. that recognize HI leaders and celebrate new eHealth initiatives, engage HI professionals in developing practice guidelines, promote health informatics as a profession, foster career progression. and continuous learning;
- f) working with health professions and educators to foster the inclusion of eHealth in the curricula for the training of health professionals, in order to build capacity to adopt eHealth in professional practice;
- g) actively employing trained HI professionals in positions that enable them to exercise and grow their capabilities, offer career path diversity and opportunity for advancement and ensure skills transfer by allowing them to mentor those who are less experienced.

6.1.5.2 Maturity model

6.1.5.2.1 Low

- a) There is no defined set of health informatics competencies and no local undergraduate eHealth training available.
- b) Where short courses are available, they tend to focus on specific systems or disease management programs.
- c) Within the public sector there are few positions dedicated to eHealth and occupied by skilled individuals.
- d) There is no career path for eHealth and necessary functions are usually performed by health professionals or by information technology staff who lack the broader skill set of a health informatics professional.
- e) There is no strategy for capacity building.
- f) There are no mentoring opportunities or other skills transfer opportunities.
- g) Lack of broadband capacity is a challenge to distance learning.

6.1.5.2.2 Medium

- a) A set of core competencies has been adopted and contextualized for the country's current eHealth needs.
- b) There is some eHealth training available at both undergraduate and postgraduate levels in the country.

- c) Some short courses are available for bridging, for specific subject areas and knowledge updates and for refresh, but they are infrequent and not widely accessible.
- d) Career paths and mentoring opportunities are emerging as individuals who have acquired broad HI capability gain experience working as consultants on eHealth projects.
- e) In the public sector there is no clear eHealth structure, but there are a growing number of positions dedicated to eHealth and occupied by skilled individuals; a strategy for capability and capacity-building is under discussion or in the planning stages.
- f) Local conferences and workshops also allow some skills transfer and added opportunities to establish mentoring relationships. There is some international collaboration but it depends on the availability of funding for travel.
- g) In some urban areas, there is enough broadband capacity for distance learning.

6.1.5.2.3 High

- a) A widely understood set of core competencies is in place, which are well-aligned with educational curriculum in an array of health informatics education programs (at both undergraduate and postgraduate levels in more than one HEI in the country).
- b) Short courses are also accessible for bridging, specific subject areas and knowledge updates and refresh.
- c) In the public sector, there is a clear eHealth structure with all or most positions occupied by HI skilled and motivated individuals.
- d) The country has a career path for eHealth and implements a strategy for capacity building.
- e) There is a high degree of skills transfer and mentoring within the profession, with ongoing international collaboration.
- f) eHealth professionals are registered with a professional body that ensures that they are trained to a specified standard for their occupation and act according to the ethical principles upheld by that body and in keeping with an increasingly well-defined set of best practices.
- g) Sufficient broadband capacity allows distance learning across the country

6.1.5.3 Examples of applicable standards, cross-references, and dependencies

Standards – no known standards identified.

Cross-references - capability and capacity development impacts all other domains either directly or indirectly.

Dependencies:

- a) Policies: national eHealth policy, eHealth capacity building strategy, human resources policy, higher education policy.
- b) Human resource capacity in the Health Ministry, larger healthcare delivery organizations/enterprises and in HEIs.
- c) A well understood set of HI core competencies and practice expectations.
- d) Financing of HEIs, short courses, conferences, international collaborations.
- e) Professional body for eHealth professionals.
- f) Physical infrastructure, broadband connectivity.

6.1.6 eHealth financing and performance management

6.1.6.1 Description

Implementing a national eHealth program requires a multi-year commitment to a series of investments, as well as development of the required governance, policies, legislation, skilled human resources, infostructure, and performance management necessary to sustain the eHealth program and to optimize (and measure) the health system benefits.

eHealth financing needs to pay not only for the ICT solutions, but for the necessary human resources including redeployment from existing activities, such as health workers' engagement and time for training. These resource impacts vary over time, so short, medium, and long term financial planning is needed to ensure this area is adequately addressed on an ongoing basis. The more sophisticated the eHealth architecture, the greater the requirement for extra finances (designated or targeted to the eHealth program) and redeployed finances and the greater the exposure to financial risk.

Performance needs to be measured along several dimensions, including the impacts on subjects of care (patients, clients, individuals), overall population health, healthcare providers, and health workers including teams, healthcare organizations, health system administrators, managers, and planners as well as the overall functioning of the health system across the continuum of care. In particular, eHealth is expected to contribute to improved health status of the population, better health resource utilization and efficiency, increased quality of care, improved outcomes for patients, and greater satisfaction for health workers. Generally, the more sophisticated the eHealth architecture, the greater the opportunities for improved performance, but over a longer timescale which requires management of expectations regarding benefits and gains.

Developing an overarching comprehensive budget estimate allows politicians, health authorities, and citizens to understand the full extent of the eHealth initiative. This will equalize expectations regarding that very sensitive subject and will prevent stressful ad hoc decision making. Provisions and methods for periodic revision of the budget must also be established, taking into account several factors such as performance, new opportunities, and changes in the eHealth environment.

The increased costs of strategic investment in eHealth initiatives and architecture should be offset by increased benefits from improved health system performance and the associated benefits over a longer-term timescale averaging 8-10 years. However, realization of these health system benefits requires a disciplined approach and strategy with a focus on managing the investments, early development and implementation of an appropriate benefits evaluation framework and related metrics, and realizing the benefits post-implementation.

Strategies for financing and ensuring the performance of eHealth investments typically include the following:

- a) continually ensuring the eHealth strategy is not only aligned with, but is seen by the public, politicians and health leaders as an important enabler for, health system reform and priorities;
- b) establishing a target benchmark (e.g. 3 % to 5 %) for eHealth spending as a proportion of overall healthcare spending, as well as the metrics for tracking IT spending and reporting against that goal;

NOTE This goal must be supported by evidence, for example from high-performing health systems (and other industries that have gone through positive transformative change) that only achieved their business goals with a sustained IT investment of at least this target rate.

- c) ensuring that eHealth strategies are multi-year in nature and that funding commitments include both out-year capital and operating cost impacts for all stakeholders (national and local), so that projects don't start and stop with fiscal year-ends or with changes in government, or falter when projects are implemented and must be sustained by local organizations;
- d) including an adoption and benefit realization component in all major projects. It is important to be able to provide clear evidence of the benefits (both direct financial benefits as well as more indirect or downstream impacts on patient care and, whenever possible, on population health), and to

recognize that benefit realization in healthcare typically requires a sustained investment in change management (process and people), since transformative change rarely happens immediately after a system goes live;

- e) basing decisions for major new eHealth investments on a clearly documented business case for the investment which addresses the costs, benefits, and risks, this is particularly true when there is significant competition for relatively scarce health capital funding. A clear business case up-front is also a strong motivator for not only focusing on delivering a successful project from an IT delivery perspective, but also ensuring the entire team (including the program sponsors) are very focused and accountable for delivery of the health system benefits involved. Business cases are more effective motivators when clearly aligned with the existing overall objectives, so that it is possible to demonstrate that the chain of business cases is the realization of the eHealth strategy.

eHealth implementations have to be financed throughout all the phases of the eHealth lifecycle:

- a) developing the business case, the system requirements and engaging stakeholders;
- b) procurement and implementation, including not only the technology, but also the project management, staff training, and change management (the bulk of the cost is in this phase);
- c) annual running costs of operating the system, refreshing the technology, and introducing enhancements to reflect changing healthcare delivery needs and achieve further benefits.

6.1.6.2 Maturity model

In low, medium, and high maturity settings, the planning, allocation, and monitoring of eHealth financing will vary according to

- a) whether there is an enterprise architecture aligned to an eHealth strategy and the extent to which it is able to guide planning, procurement, and standardization,
- b) the way eHealth financing is planned and allocated, and the degree to which it is founded on a well-documented business case establishing clear metrics for the project and its benefits,
- c) the characteristics of the model used for financing eHealth projects,
- d) the extent to which guidelines are mandated for eHealth procurement, and
- e) the degree to which expenditure on eHealth implementations is monitored and the impact evaluated.

6.1.6.2.1 Low

- a) National enterprise architecture work has not been initiated.
- b) Some initial eHealth investments are made but financing is not based on any overarching strategy which ensures that the systems being implemented will integrate well together.
- c) The planning of eHealth financing has the following characteristics:
 - 1) financing of eHealth is fragmented and linked to the organizational structure, resulting in funding of vertical applications within programs;
 - 2) planning tends to respond to short-term priorities and not to longer term national strategic priorities for healthcare;
 - 3) investment is often prioritized for more basic infrastructure such as electricity and telephones;

- 4) goals and objectives for eHealth in the short and medium term are focused on public health requirements: providing health information indicators, tackling the burden of disease, and capacity building.
- d) The model for national financing of eHealth has the following characteristics.
 - 1) There is persistent reliance on donor funding which is, in turn, affected by economic trends and the policies of other country governments.
 - 2) Financing is typically limited to ICT vendors and associated services, with no allowance for the costs of the participating healthcare delivery organizations as well as post-implementation costs for change management and ongoing sustainment of the new system.
 - 3) Pilot projects are funded, without multi-year funding in place that can be accessed to move ahead with broad scale implementation.
 - 4) eHealth is not included in the overall healthcare budget as a separate requirement.
 - 5) The national model of financing for healthcare directly impacts the level of eHealth investment.
- e) Procurement:
 - 1) Procurement is largely supply driven and not needs driven.
 - 2) There are no mandatory guidelines for procurement.
- f) Monitoring and Evaluation:
 - 1) There is no monitoring and evaluation to assess the impact of eHealth implementations on the delivery of healthcare services, or a requirement for a business case establishing the cost and benefit goals for the project.
 - 2) There is no monitoring and evaluation of resource allocation, change management or risk management.
 - 3) There are no policies, regulations, legislation, or structures in place for the governance, administration, and monitoring of eHealth implementations.

6.1.6.2.2 Medium

- a) Some national enterprise architecture work has been done which supports the following.
 - 1) The alignment of ICT investments with the goals of the healthcare system.
 - 2) Identification of economies of scale that may be achieved through convergence of eHealth systems with common requirements.
 - 3) Investigation of standardization in order to
 - i) drive down costs,
 - ii) identify systems posing challenges for standardization and interoperability, e.g. where donor-funding has resulted in a wide range of separate initiatives, and
 - iii) obtain agreement between policy makers, donors, and industry on the adoption of standards and best practices.
 - 4) Leveraging or merging with other government ICT initiatives where practical.
- b) The planning of eHealth financing has the following characteristics.
 - 1) Planning of large projects is related to national strategic priorities for healthcare.

- 2) Financing is planned within the medium term budget framework and is largely project based.
 - 3) Financing takes major costs into account but does not always include risks and net benefit calculation.
 - 4) Planning is constrained by high costs and lengthy implementation times.
 - 5) The enterprise architecture may assist with planning and investment by providing some foundation for the allocation of resources.
 - 6) Some large-scale, long-term projects may be operationalized and decoupled from political cycles.
- c) The model for national financing of eHealth has the following characteristics.
- 1) The national model of financing for healthcare directly impacts the level of eHealth investment.
 - 2) eHealth implementations are largely funded by capital financing, competitive grants and philanthropy which are in turn affected by economic trends and the policies of other country governments.
 - 3) eHealth is treated as a line item in the overall healthcare budget and must compete for scarce resources with all other parts of the healthcare value chain, rarely getting more than 2 % of the overall budget.
 - 4) There are isolated instances where alternative financing models are used, e.g. public private partnerships (PPPs).
 - 5) Multidisciplinary relationships are explored as alternatives for funding.
 - 6) In general, funding is not informed by realistic and clearly specified returns on investment.
 - 7) Public health status trends are rarely used to project financial requirements.
 - 8) Economic decisions are not separated from financing decisions.
- d) Procurement:
- 1) Procurement is largely supply driven and not needs driven.
 - 2) Basic policy and guidelines on procurement have been developed.
- e) Monitoring and evaluation:
- 1) There is limited monitoring and evaluation to assess the impact of eHealth implementations on delivery of healthcare services.
 - 2) There is limited monitoring and evaluation of resource allocation, change management or risk management.
 - 3) There are limited policies and structures in place for the governance, administration and monitoring of eHealth implementations.
 - 4) The impact of the installation of essential foundational infrastructure, which may on its own not yield benefits, is difficult to assess.
 - 5) Evaluation may be complicated where the entities benefitting from eHealth implementations are not the entities where the costs are incurred.

6.1.6.2.3 High

- a) National enterprise architecture work supports the following.
 - 1) Development of an eHealth financing strategy with a multi-year time horizon, aligned with a national eHealth strategy, which has a high degree of influence on ICT investments.
 - 2) Achievement of economies of scale through convergence of eHealth systems with common requirements.
 - 3) Adoption of standardization in order to drive down costs.
 - 4) Agreement between policy makers and industry on the adoption of standards and best practices that will speed up deployment.
 - 5) Leveraging or merging with other government ICT initiatives where practical.
 - 6) Leverage existing assets to support improvements.
 - 7) Providing a foundation for the allocation of resources.
 - 8) Reduction of redundancy and the continual measurement of return on investment.
- b) The planning of eHealth financing has the following characteristics.
 - 1) Planning is related to national strategic priorities for healthcare through the eHealth financing strategy.
 - 2) General acceptance that is up to 5 % of all healthcare investment goes towards eHealth.
 - 3) eHealth projects are operationalized and decoupled from political cycles.
 - 4) The focus is less on acquisition and more on renewal and growth of existing assets.
 - 5) Movement is from a development phase towards an innovation phase.
 - 6) Projects with high potential which utilize existing capacity are given priority.
 - 7) eHealth is seen as a mainstream activity aligned to national healthcare goals.
 - 8) Financial planning is done for the entire life-cycle of the implementation and takes into account all costs and risks in order to support net benefit realization and ensure sustainability.
 - 9) Planning for sustainability addresses all phases of the eHealth life cycle.
 - 10) Leadership is committed to eHealth and puts its weight behind financial and organizational issues.
- c) The model for national financing of eHealth has the following characteristics.
 - 1) eHealth implementations are largely funded by capital financing and revenue, with a multi-year time horizon. Very low dependency on competitive grants and philanthropy with concerted investigation into ways revenue and increased productivity can be used to fund ongoing eHealth delivery that are then committed to in the investment's business case.
 - 2) Funding tends to be more distributed than centrally spent or project-based.
 - 3) Various types of finance, e.g. public private partnerships (PPPs), leasing and loans from investment banks, World Bank, WHO, other international institutions are investigated and taken advantage of, especially for non-recurring expenses.
 - 4) eHealth investments support healthcare from within the mainstream strategic context.
 - 5) The model takes into account different investments for different types of eHealth and recognizes the need to strategically invest in infrastructure supporting future initiatives.

- 6) The model aims to make the eHealth system financially sustainable.
 - 7) Levels of eHealth investment are not affected by the model of financing health services.
 - 8) eHealth investments are interoperable and integrated and seek to bring together and address the needs of all actors in the healthcare value chain. Other eGovernment investments are also taken into account.
 - 9) A return on investment and realization of benefits is not expected in less than five years.
 - 10) The funding model is informed by realistic, achievable and clearly specified returns on investment and is clearly related to national priorities.
 - 11) Willingness to invest up front on planning the infrastructure and assessing alternative approaches.
 - 12) Investment is planned based on net benefits (cumulative costs vs. benefits over time).
- d) Procurement:
- 1) Comprehensive policies and guidelines on procurement exist and are mandated.
 - 2) Procurement is based on real needs and is not supply-driven.
 - 3) Performance and capacity of suppliers improves in order to meet articulated needs.
- e) Monitoring and Evaluation:
- 1) There is constant monitoring and evaluation in order to assess the impact of eHealth implementations on the delivery of healthcare services.
 - 2) There is constant monitoring and evaluation of resource allocation, change management, and risk management.
 - 3) There are comprehensive policies and structures in place for the governance, administration, and monitoring of eHealth implementations.
 - 4) Monitoring and evaluation systems are able to demonstrate how eHealth solutions can contribute to improvements in quality, access and efficiency and in this way boost investment in eHealth.
 - 5) There is ongoing impact analysis in order to optimize resource allocations for planned future investments and monitor existing activities.

6.1.6.3 Examples of applicable standards, cross-references, and dependencies

No specific applicable HI standards identified.

The maturity level of this component is dependent on the maturity levels and activities within all other components of national governance and ownership (see [6.1.1](#), [6.1.2](#), [6.1.3](#), [6.1.4](#), and [6.1.5](#)):

- a) executive sponsorship;
- b) national leadership;
- c) standards adoption and implementation;
- d) capacity and capability development;
- e) planning and architecture.

6.1.7 eHealth planning and architecture maintenance

6.1.7.1 Description

6.1.7.1.1 Background

The World Health Organization (WHO) defines eHealth as the use of information and communication technologies (ICT) for health.^[194] In its broadest sense, eHealth is about improving the flow of information, through electronic means, to support the delivery of health services and the management of health systems.^[93]

The case for eHealth is captured well in the opening paragraph of the International Telecommunications Union (ITU) web page on the WHO-ITU National eHealth Strategy Toolkit: Today eHealth is changing healthcare delivery and is at the core of responsive health systems. Whether to deliver care, deploy personnel, conduct research, or support humanitarian action, at every level and in every country the business of health relies on information and communication and, increasingly, on the technologies that enable it. Technological advances, economic investment, and social and cultural changes are also contributing to the expectation that the health sector must inevitably integrate technology into its way of doing business.^[195]

A plan is needed to achieve a set of desired outcomes, balancing the requirement for new functionality, and improved health outcomes for a population, while maintaining existing functionality that is core to the needs of that population. All planning should be centred on the end outcome, and in eHealth there needs to be a clear patient-centred focus, a public health focus or both for all activities. Even core infrastructure components need to be linked to health benefits, acknowledging that priorities can change as systems and capacity mature.

The first stage in any planning activity is therefore to set clear, desirable, and achievable goals in terms of real benefits that can be realized. A clear and prioritized set of health outcomes is essential, with established timelines for delivery. Further, a clear linkage with eHealth is necessary in order to determine the value of ICT investments in driving out benefits. For example, the eHealth investments to support endemic infectious diseases in an immature economy are likely to be very different from the investments to support chronic disease management in an aging population. Health priorities must drive eHealth planning and investment.

eHealth has a number of characteristics that affect planning. The flow of information electronically depends on the maturity of the environment within which it operates. Health information is rich and variable, and although there are standards for many forms of recording and exchange of information, the maturity of markets in adopting those standards varies widely. There are strong influences on the application of health informatics from many stakeholders, ranging from professionals involved in the delivery of care, through to policy makers and commissioners of services. Health information includes information related to direct care, as well as to the resources involved in the delivery of care, including workforce. The logistics pertaining to delivery and recording of care are complex and highly changeable. Simple solutions to complex problems are rarely effective.

Plans need to be robust, adaptable, and achievable. A robust plan is able to deal with changing circumstances. A good planning model considers a variety of scenarios, and should be able to respond to different pressures. Adaptability means being able to make changes to the plan without sacrificing the end goal. Achievability means being realistic and acknowledging external factors that are likely to impact the execution of the plan and the delivery of the goals. Plans should be neither optimistic nor pessimistic, but should be able to address and survive the extremes of changes in the environment. To achieve this, wide consultation and engagement is necessary in the planning activity, to ensure that plans meet the needs of all or nearly all stakeholders in all or nearly all circumstances.

Planning can be central or distributed, tactical or strategic. Centralized strategic planning is likely to occur only in stable environments, and a substantial eHealth architecture will depend heavily on the environment in which it is implemented. Nevertheless, it is often viable for nations with a poor eHealth infrastructure to plan and deliver effective eHealth initiatives that meet the most important needs of